- If possible, inform the emergency facility prior to the arrival of the potentially contaminated patient. At a minimum notify all emergency medical personnel of the extent and type of contamination on the injured person to the extent possible.

10.3.2 Vehicle assessment and disposition

Specific areas must be designated and identified near the CCC in advance for vehicle decontamination, contaminated vehicle storage, and entry/exit areas for vehicle access to the hot zone.

- Upon arrival, the field team vehicle shall follow the signs and directions of the hotline personnel as they approach the hotline area. Normally, vehicles will be directed to an area separate from the CCC for an initial survey.
- The person or persons who are assigned to process arriving field teams shall have the final authority as applied to all approaching traffic.
- In the event more than one field team arrives at the initial survey area, only one vehicle at a time shall be processed unless otherwise directed by the hotline personnel. All other vehicles shall wait at the appropriate rally point until additional instructions are received.
- Hotline personnel will then perform a survey of the field team's vehicle external surfaces and tires/wheels to determine the extent of external contamination on the vehicle. Radioactivity on the vehicle engine air filter should be assessed to indicate whether or not the vehicle may have entered an area of airborne contamination. One of the following decisions will then be made concerning the disposition of the vehicle:
  - The vehicle may be allowed to continue processing into the uncontaminated area if there is no detectable contamination in or on the vehicle.
  - The vehicle may be held for decontamination in a designated area.
  - The vehicle may be held as contaminated equipment and allowed to be returned to the field for continued operations if the contamination levels do not pose a health hazard to the vehicle operators.
  - The vehicle may be removed from service and identified as contaminated and no longer useable by field teams due to high exposure rates, as determined by the Safety Officer and incident management personnel.
- Hotline personnel will then allow for the field team to disembark from the vehicle whereupon they will survey the vehicle interior to identify contaminated areas. This will occur prior to removing equipment or samples from the vehicle or passing into the hotline area.

Note: At this time, field team personnel should perform self-assessment surveys to identify contamination on their PPE.

- Forms for survey and wipe collection can be found in SOP RPR-271, *Wipe Procedure for Removable Contamination*, and SOP RPR-330, *Survey Techniques for Contamination Control and Exposure Rate Monitoring*.

10.3.3 Sample Receipt and Sample Control

- A specific area must be made available for field teams to transfer custody of their samples to Sample Control. A table with appropriate equipment and staffed by experienced personnel should be placed between the vehicle assessment area and the contamination reduction corridor as shown in the diagrams in appendix 17 of this SOP.
- Samples must be double bagged (refer to SOP RPR-220, "Environmental Sampling Procedures") prior to transfer to Sample Control to assure that all precautions have been taken to prevent transfer of external contamination at the hotline.
- The original copy of the Sample Control Form must be inserted between the sample bags in such a way that all parts of the form are visible and legible.
- Additional or carbon copies of forms shall be surveyed for contamination prior to transfer to Sample Control. Contaminated forms shall be bagged individually, or as instructed by Sample Control personnel.
- All Sample Control Forms associated with samples deposited at the hotline must show the exposure rate on contact recorded in the appropriate location on the form, and be in the appropriate units.
- Sample Control personnel have the full authority to reject any sample if the forms that are returned with the sample are not complete and legible, or if removable contamination is present on the external portions of the sample bags.
- Sample Control personnel will receive and seal the sample into a third plastic bag at the Sample Control table for processing after sample documents have been reviewed.
- Sample Control personnel shall be responsible for identifying and processing the sample based on sample priority, as well as any need for segregation due to high exposure rates.

10.3.4 Responder Equipment Assessment and Handling

- The field team is required to maintain survey and sampling equipment as free from contamination as is reasonable to limit excessive exposures and cross contamination. If equipment is returned from the field with external contamination, each item will be processed individually.
- The hotline team, coordinating with the Instrument Manager and the Logistics Officer, and with assistance from the field teams, will evaluate contaminated field instruments and equipment to determine the extent of contamination. It is the responsibility of the hotline team to identify contaminated equipment to field teams that re-use it.
- A specific area will be available for field teams to drop off equipment and instruments where they can be evaluated and held for processing.

- If equipment that is returned from the field is to be passed into the clean zone, necessary survey and decontamination activities will be made at the hotline to assure that the items are actually clean.
- In the event items are to be returned to the field, appropriate effort will be made to assure that items are clean to reduce the potential for cross contamination, or that any fixed contamination present is identified and marked.

10.4 Contamination Control Corridor (CCC) Operations

The CCC must be a strictly controlled operation consisting of separate corridors for handling and decontamination of equipment received from the field; and additionally for survey, decontamination, and release of personnel that have returned from field operations. All entrances to the CCC must be controlled by hotline personnel.

10.4.1 Arriving personnel will follow all hotline personnel instructions during the entire CCC transition.

10.4.2 All equipment and field samples shall be processed at the corresponding areas prior to entry into the CCC. Refer to sections 10.3.3 and 10.3.4 for more information.

10.4.3 Field personnel should make every effort to limit the spread of contamination as they approach the hotline area. Precautions to be taken include:

- Keep all samples and documentation clean, with one field team member responsible for handling and keeping documents and samples in uncontaminated condition as much as reasonably achievable.
- All equipment that is used in the field should be maintained in as much of an uncontaminated condition as possible to prevent unnecessary contamination being transferred into the hotline area.
- Field personnel will not deviate from the marked pathways or instructions provided at the hotline. This will limit the spread of contamination to other controlled areas.

10.4.4 Access to the CCC should be done individually and in a controlled manner, following the instruction of the responsible hotline operator. The person who is being processed should make every attempt to avoid touching or handling hotline equipment such as the portal monitor, hand held instruments, or any other items in the CCC area. The CCC should have areas that are designated for bracing, or for personnel to lean against, if support is needed.

10.4.5 All personnel surveys shall be performed and documented according to the guidelines in SOP RPR-850.

10.4.6 All efforts at decontamination of personnel shall be performed and documented according to the guidelines in SOP RPR-851.

10.4.7 CCC process

Refer to the appendix 17.3, *Hotline Operational Flowchart* for additional information regarding the hotline doffing process. The following is the recommended series of steps in the CCC process from initial entry through the final survey and exit.

1) Remove PPE tape with the assistance of the hotline operator, disposing of the tape into the appropriate waste receptacle.
2) Following instruction from hotline personnel and stepping into the next area of the CCC, doff and dispose of outer boots and gloves. Chairs and other support items should be provided for this activity.
3) Step on the entry step-off pad with both feet, followed by entry to the CCC through the initial portal monitor. If no portal monitor is present, the hotline operator will perform the initial survey using an appropriate handheld contamination detection instrument.
4) DECISION POINT – If the person is excessively contaminated (risk of spread of contamination exists) the person should be directed to the GROSS DECONTAMINATION AREA adjacent to the hotline for special assistance with the removal of PPE and then decontamination followed by survey and release.
5) Lower hood and remove respirator with the assistance of the hotline operator, using caution to avoid spread of potential contamination to the hair or the skin around the face. The respirator should be surveyed and dropped at the appropriate point for decontamination if needed. If the respirator is clean, it shall be returned to the owner for cleaning and re-use.
6) At this point, hotline personnel shall survey around the areas of the face and hair that were in contact with the respirator. If contamination is present, the contaminated person should be directed to the decontamination area after all doffing is complete, for decontamination and re-survey prior to exit from the CCC.
7) Continue removing PPE, including coveralls (Tyvek or other), inner boots if used, and inner gloves, disposing of items at the direction of the hotline operator and into the appropriate containers.
8) After all PPE has been removed, the hotline operator will then perform a complete and comprehensive survey for contamination on the individual using an appropriate contamination detection instrument.
9) If no contamination is found, the surveyed person shall exit the CCC by stepping onto a sticky step-off pad and through a second portal monitor, if available. The individual will then collect any personal PPE released by the hotline personnel.
10) If contamination is present, the contaminated person should be directed to the decontamination area after all doffing is complete, for decontamination and re-survey prior to exit from the CCC.

10.5 Re-entry

10.5.1 If the field team or specific field team personnel will return to the field after activities not requiring decontamination - such as transfer of samples, replacing equipment and/or supplies, or other activities not associated with decontamination - personnel can proceed directly back to the hot zone without interaction with the CCC to continue monitoring and sampling assignments.

10.5.2 If personnel will return to the hot zone, but will require special services that will require decontamination, or decontamination surveys such as PPE replacement or repair, some doffing must occur. Personnel will enter the CCC and proceed to the point where the PPE in question can be removed and replaced. Once PPE is repaired and re-donned, personnel may then re-enter the contaminated areas.

10.5.3 If the team is exiting from the contaminated area (i.e. to rest or to replenish fluid levels) then the team must follow the complete doffing and exit process. All food and drink must be maintained in the clean area only. When the team is ready to re-enter the hot zone, they will re-don all appropriate PPE prior to re-entry.

10.6 Waste Management

10.6.1 All PPE that is contaminated must be segregated into separate marked containers for disposal as Rad-Waste. The containers must be easily identifiable and appropriately labeled. Any PPE that has not been proved to be uncontaminated must be treated as contaminated.

10.6.1 Any waste product that is verified as clean by hotline personnel can be collected as regular waste, and disposed of using routine methods for garbage disposal. Absolutely NO contaminated material, sharps (knives, cutters, etc.), or hazardous non-radioactive materials can be disposed of in this waste stream.

10.6.3 If waste water is generated by the hotline from decontamination operations, it shall be collected to prevent surface waters or clean waters from being contaminated. If it is possible, set up an evaporation pond to deplete the amount of waste, or store the water for analysis and determination of the appropriate disposal method. Decisions regarding the disposal of waste may require input from stakeholders, incident management, and other resources to assure that an appropriated method of disposal is used so that no additional harm will come to the environment or public.

10.7 Hotline Demobilization

Planning for hotline demobilization should be considered as soon as possible after the deployment of the RERT. The need for packing and transportation of materials and personnel, disposition of waste materials, shipping and tracking of samples, and records management are all important issues that must be considered well before the need for actual demobilization.

Hotline demobilization will be initiated under the following conditions:

- RERT Commander (or organizational equivalent) sends order to demobilize. The logistics officer begins to process all equipment, vehicles, and personnel for packing and transport.
- The hotline/decontamination area leader ensures all equipment, vehicles, and personnel are properly surveyed and inventoried. If any areas of contamination are identified on personnel

and/or on equipment, these areas must be cleaned and decontaminated prior to packing and transport.

- The Incident Commander and/or RERT Commander shall be notified immediately if any contaminated vehicles or equipment cannot be decontaminated. A description of these unrecoverable items along with the extent of contamination and their current location must be included.
- All remaining hotline equipment will be properly packed in the associated transport containers. Any tents, chairs, or other support equipment that cannot be containerized will be folded and packed. After all equipment, materials, and supplies are properly packed, the hotline/decontamination personnel will coordinate with the Logistics Officer for loading and transport arrangements.

11.0 QUALITY ASSURANCE

11.1 Quality Control

11.1.1 Maintain a clean work environment and use appropriate survey and decontamination procedures to avoid the spread of contamination.

11.1.2 Clearly identify all receptacles for waste materials. All radioactive and non-radioactive waste containers must be segregated and be of different colors. Use Radioactive Waste labels only when appropriate.

11.1.3 Take precautions to prevent contamination of documents or records that may be generated during hotline/decontamination operations. Ensure that all records are processed appropriately and removed from the hotline area to prevent loss or damage.

11.1.4 All radiation detection instruments must have been calibrated within the previous 12 months and must display a calibration label with the calibration date and calibration due date. A current calibration certificate must also be kept available or in the project file for each instrument that is used on the Hotline.

11.1.5 Wipe counters that are used at the hotline will be checked for proper operation at the beginning and end of each operational shift by the hotline team and verified to be within acceptable response criteria identified in SOP RPR-354, *Operation of the Ludlum Model 2929 Dual Channel Scaler* or equivalent project planning documents prior to use. Background count rates for alpha and beta radiation shall be initially established and then shall be monitored at least once for every two hours of operation. The background values and control checks shall be documented and a control chart of the background measurements will be maintained in a project log kept with the instrument.

11.1.6 Portal monitors shall be operationally checked by the hotline team at the beginning and end of each operational shift. The hotline personnel shall setup and manage the portal monitors as described in SOP RPR-850 or equivalent project planning documents. The background values and operational checks shall be documented and a control chart of the background measurements will be maintained in a project log kept with each instrument.

11.1.7 Hotline instruments shall be operationally checked by the hotline team at the beginning and end of each operational shift. The hotline personnel shall maintain all instruments in a clean and uncontaminated condition during use. In the event the instrument or detector should become contaminated, it shall be returned to the Instrument Manager for assessment and decontamination. The instrument Manager (or appropriate ICS equivalent) shall be responsible for record keeping associated with each particular instrument issued to the hotline.

11.2 Records Management

All records pertaining to environmentally related measurements and all documents relating to the Quality System must be archived, retained and disposed of according to the requirements in the NRCFO QMP and the CRPR QAM

11.2.1 Procedures must be in place for managing field team documents that are processed at the Sample Control station, and are the responsibility of Sample Control personnel. All records generated by Sample Control personnel must be handled according to SOP RPR-810, *Sample Control Operations*. This may include but is not limited to copies of sample control forms, chain-of-custody forms, field monitoring logs, and other field team documents.

11.2.2 Copies of documents generated by the field teams or hotline personnel that are separate from Sample Control documents should be created and added to the project file. The original versions of these documents/forms should be submitted to and archived by the appropriate documentation unit (FRMAC or ICS) or Project Manager as appropriate. These documents may include decontamination forms, equipment release forms, quality control check forms, hotline survey logs, etc.

11.2.3 Logbooks must be maintained according to the requirements described in the NCRFO QMP and CRPR QAM unless specific instruction is provided in project planning documents. Logbooks are issued upon request by the QA Manager and once complete, are archived with the QA Manager.

11.3 Computer Hardware and Software Management

There are no specific requirements in place for the management of computer hardware or software associated with hotline operations at the time of this writing. Some federal organizations are in the process of transition to computer based documentation for recording data and will require management processes to be defined when the programs are established.

11.4 Procurement Requirements

All procurements shall be made following the requirements in the Federal and EPA acquisition regulations as stated in NCRFO QMP. The use of purchase cards for procurement must follow the NCRFO Purchase Card Policy.

11.5 Assessments

11.5.1 This SOP shall be reviewed at least once annually to assure that the procedures are appropriate and comprehensive.

11.5.2 The effectiveness of this procedure shall be evaluated at least annually by those personnel immediately responsible for overseeing and/or performing the tasks described by the procedure. Results of any review shall be used to improve the process and to revise this

SOP and related quality documentation. Results shall also be documented per SOP RIE-101.

11.5.3 This document must reflect the quality requirements for all organizational parts of NCRFO. If changes to the organizational structure of NCRFO occur, this document must be reviewed and revised to reflect those changes.

11.6 Corrective Quality Actions

If a procedural non-conformance is discovered or one occurs due to unforeseen circumstances, the non-conformance issue must be documented and corrective action process followed as defined in the CRPR QAM and the NCRFO QMP.

12.0 DATA ANALYSIS AND CALCULATION

N/A

13.0 DATA REVIEW

13.1 Field sample documentation must be reviewed for completeness and accuracy by the field team that collected the sample prior to transfer to the custody of Sample Control. All forms or other documentation associated with each sample must be accounted for by the field team.

13.2 Sample Control is responsible for the distribution of documents associated with ER samples collected in the field to the appropriate data management unit, whether in a FRMAC or an ICS management organization. For field projects, the Project Manager is ultimately responsible for the processing and archive of project related documents as required by the project planning documents.

13.3 All documents generated at the hotline, including survey diagrams or forms, personnel decontamination diagrams or forms, or any other data associated with personnel survey or decontamination operations, including copies of logbook information, will be identified as Personally Identifiable Information (PII) For Official Use Only (FOUO), and processed according to Sample Control procedures. All procedures established to protect personal information generated by hotline personnel will be followed.

14.0 METHOD PERFORMANCE

N/A

15.0 ENVIRONMENTAL MANAGEMENT SYSTEM

15.1 Pollution Prevention

15.1.1 It is expected that contaminated materials in the form of PPE, plastic bags, plastic sheeting, will be left for disposal at the CCC. It is important to segregate and contain contaminated materials to prevent the spread of contamination into the environment.

15.1.2 If contaminated water is part of the waste stream for the CCC and decontamination activities, careful planning must be made to assure that all contaminated water is contained at the CCC facility in appropriate storage containers, or evaporation ponds.

15.1.3 In some cases the wastewater generated during operations at the CCC could potentially be re-directed back to previously contaminated areas for later cleanup, or into local waste streams for treatment. These options should only be considered as a last resort and must have the approval of all stakeholders (local governments and public).

15.2 Waste Management

15.2.1 Segregate all contaminated and non-contaminated waste materials early in the CCC process. Do NOT place contaminated waste into containers that are identified and marked for **non-contaminated** waste. The non-contaminated waste can be disposed of using normal waste stream methods.

15.2.2 All contaminated materials (tools, overalls, etc.) collected during CCC operations must be placed into containers that are clearly marked and identified as contaminated. These items must be disposed of following regulatory requirements for the type of waste being generated (low level radioactive, mixed waste or hazardous waste, etc.). Contain and segregate these materials and coordinate their removal and proper disposal with the Safety Officer for the response.

16.0 REFERENCES

16.1Specifications and Requirements

16.1.1 Center for Radiation Preparedness and Response, Standard Operating Procedure RPR-330, *Survey Techniques for Contamination and Exposure Rate Monitoring,* August 2013

16.1.2 Center for Radiation Preparedness and Response, Standard Operating Procedure RPR-850, *Personnel Monitoring for Contamination*, August 2013

16.1.3 Center for Radiation Preparedness and Response Standard Operating Procedure RPR-851, *Emergency Response Personnel Decontamination Procedure*, August 2013

16.1.4 Center for Radiation Preparedness and Response, *Quality Assurance Manual,* Revision 0, August 2013

16.1.5 Radiation and Indoor Environments National Laboratory, *Quality Management Plan,* Revision 4, May 2012 (also NCRFO QMP)

16.1.6 Radiation and Indoor Environments National Laboratory, Standard Operating Procedure RIE-101 R6, *Standard Operating Procedure Development*, Aug. 2012

16.2 Guidance Documents or other special references

16.2.1 Transportation Emergency Preparedness Program, Department of Energy, Office of Transportation and Emergency Management, *Model Procedure for Radioactive Material or Multiple Hazardous Materials Decontamination*, Revision 4, Jan. 2007

16.2.2 Occupational Safety and Health Administration, *Guidance Manual for Hazardous Waste Site Activities*, DHHS (NIOSH) Publication No. 85-115, Oct. 1985

16.2.3 American National Standards Institute, *American National Standard Radiation Protection Instrumentation Test and Calibration, Portable Survey Instruments*, ANSI N323A-1997

16.2.4 Center for Radiation Preparedness and Response, Standard Operating Procedure RPR-220, *Environmental Sampling Procedures*, August 2013

16.2.5 Center for Radiation Preparedness and Response, Standard Operating Procedure RPR-271, *Wipe Procedure for Removable Contamination*, August 2013

16.2.6 Center for Radiation Preparedness and Response, Standard Operating Procedure RPR-354, *Operation of the Ludlum Model 2929 Dual Channel Scaler*, August 2013

16.2.7 Center for Radiation Preparedness and Response, Standard Operating Procedure RPR-803, *Sampling Equipment Decontamination*, August 2013

16.2.8 Center for Radiation Preparedness and Response, Standard Operating Procedure RPR-810, *Sample Control Operations*, August 2013

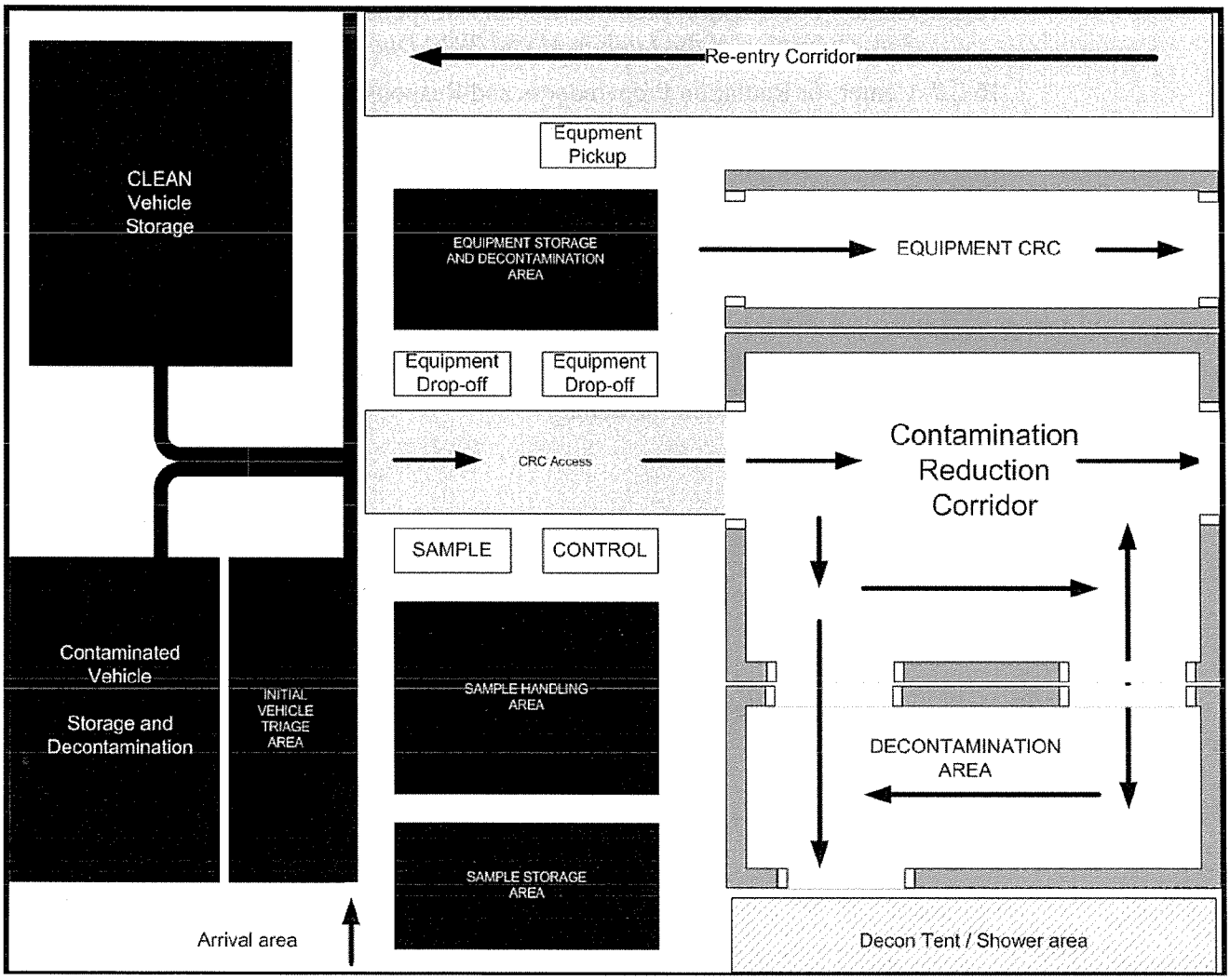
17.0 APPENDICES

17.1 Diagram: Overview of Hotline layout for standard radiological operations

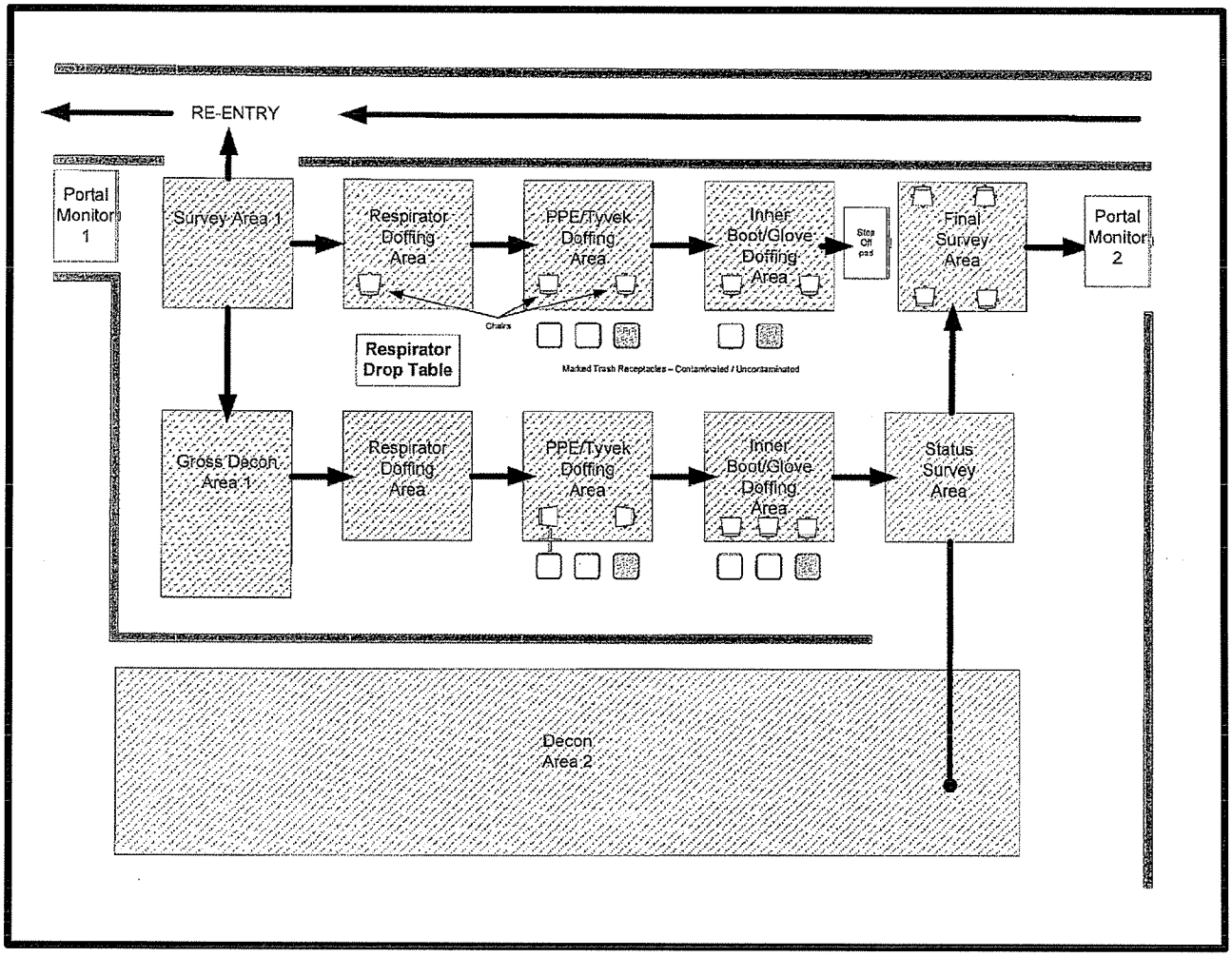
17.2 Diagram: Contamination Reduction Corridor, detail

17.3 Diagram: Hotline Operation Flowchart

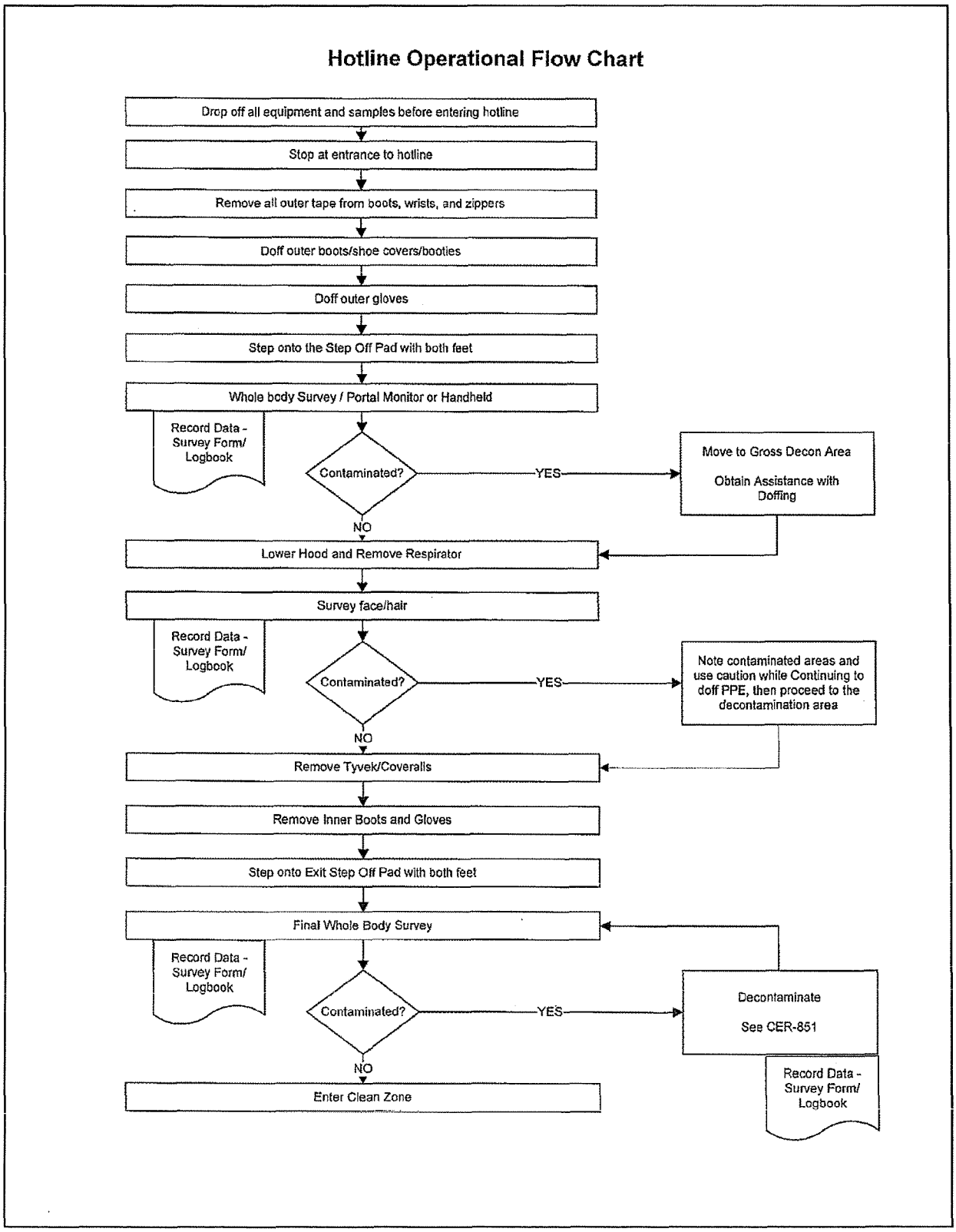
17.1 Diagram: Overview of Hotline layout for standard radiological operations (not to scale)



17.2 Diagram: Contamination Reduction Corridor, detail (not to scale)



17.3 Diagram: Hotline Operational Flowchart



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Personnel Monitoring for Contamination

Responsible Official: Suzanne Beimer Date: 7/29/2013

Technical Review: [signature] Date: 7/29/13

Approved By: Mark D. Sen Date: 7/29/2013
CRPR Quality Assurance Coordinator (QAC)

Approved By: [signature] Date: 7/29/13
CRPR Center Director

Approved By: [signature] Date: 7/29/2013
NCRFO QA Manager

Approved By: [signature] Date: 7/29/2013
NCRFO Director

ANNUAL REVIEW

RO Review/Date: _____ Quality Review/Date: _____

RO Review/Date: _____ Quality Review/Date: _____

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SOP REVISIONS

Rev. No.	Rev. Date	Revision	Responsible Official
00	11/09/ 2012	Initial Issue	L. Kelly
01	05/30/2013	Put into RIE-101 R6 format and made consistent with the RPRMER QAM, organizational name changes and boiler plate language.	L. Nguyen

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1.0 PURPOSE

During emergency response or field activities, personnel may become potentially contaminated with radioactive material. Contamination can be transferred to clothing, tools, equipment, objects, and/or body parts coming in contact with the radioactive material. To identify contamination located on personnel's skin, clothing, or personal protective equipment, personnel must be monitored for contamination using the appropriate radiation instrumentation. Proper surveying techniques must be performed for each personnel especially when personnel are exiting a controlled area. The purpose of this procedure is to describe techniques used by Field Monitoring Specialists to survey personnel who have become potentially contaminated with radioactive material during a response or field activity.

2.0 SCOPE AND APPLICABILITY

2.1 Scope, Application, Method Summary

2.1.1 Surveying procedures can vary depending on the type of radionuclides present and the chemical form of the contaminant. Before surveying efforts begin, the Field Monitoring Specialist must know the type and chemical form of the contaminant to determine the appropriate instrumentation to use for surveying.

2.1.2 This procedure does not describe common decontamination procedures used for removing contaminants from external surfaces of the body. For more advanced decontamination procedures, please refer to Standard Operating Procedure (SOP) RPR-851 *Emergency Response Personnel Decontamination Procedure.*

2.1.3 Personnel equipment, tools, vehicles, and/or objects brought into the field may potentially come in contact with radioactive material. Decontamination of sampling equipment will help minimize the potential spread of the contaminant to personnel. This procedure does not address decontamination of sampling equipment. For instructions on decontaminating sampling equipment, please refer to the SOP RPR-803 *Sampling Equipment Decontamination.*

2.2 Interferences

2.2.1 Some radiation instrumentation has an external source located on the side of the detector for field instrumentation operational checks. If the probe is turned in the same direction as the source, a false positive reading may occur. Always face the detector away from any external source that maybe present in the field and/or near the detector (e.g. a check source located on the side of the detector) to prevent a false positive. Resurvey the area to ensure correct reading.

2.2.2 If high levels of contamination are found on personnel, the range of the instrumentation may need to be increased by increasing the scale on the meter body (e.g. if the scale of

the meter is "X1", increase the scale to "X10"). Always remember to reset the instrument before and after changing scales by pressing the red "reset" button before continuing to perform the personnel survey.

2.2.3 The Field Monitoring Specialist must be cognizant of the type and physical form of the contaminant. Moisture on personnel's skin may attenuate alpha particles making it difficult to detect.

2.3 Potential Problems

Personnel who are working in contaminated areas may become internally contaminated. External contamination may enter the body via absorption, inhalation, injection, and/or ingestion. If internal contamination is suspected, immediately contact the Radiation Safety Officer (RSO) for further additional monitoring and dose analysis. This procedure does not address internal contamination.

3.0 DEFINITIONS

3.1 ALARA — As low as reasonably achievable. The aim is to minimize the risk of radioactive exposure while keeping in mind that some exposure is acceptable and necessary, in order to accomplish the given task, or mission.

3.2 Contamination — The deposition of radioactive material in any place where it is not desired.

3.3 Cross Contamination—contamination of the PPE or personnel caused by the introduction of a contaminant from another location

3.4 CRC or CCC — Contamination Reduction Corridor or Contamination Control Corridor

3.5 Decontamination — The process of removing radioactive contamination from clothing, tools, equipment, objects, vehicles, and/or body

3.6 Field Monitoring Specialist—describes personnel located within or near the hotline whose duties include surveying personnel and/or equipment for contamination, locating contamination, and resurveying to determine the success of decontamination efforts.

3.7 Hotline—An area where samples are received and processed, personnel, equipment, and vehicles are surveyed, and decontamination operations can be performed. The Hotline can also be referred to as the 'Contamination Reduction Corridor' or 'Contamination Control Corridor'.

3.8 PPE — Personal Protective Equipment, including but not limited to respiratory protection devices, protective clothing, gloves, boots, and boot covers, etc.

4.0 PERSONNEL

4.1 PERSONNEL QUALIFICATIONS

4.1.1 Personnel who perform the tasks described in this SOP must be provided with training, followed by demonstration of proficiency. If training courses are not available, personnel will learn to perform this procedure under the direct supervision of a Subject Matter Expert (SME). Training and demonstrations of proficiency must be performed and documented in accordance with the Center for Radiation Preparedness and Response (CRPR) Quality Assurance Manual (QAM) and must be consistent with the National Center for Radiation Field Operations (NCRFO) Quality Management Plan (QMP, also R&IENL QMP).

4.1.2 Personnel who perform the tasks described in this SOP must have received radiation safety training within a 12-month period as specified in the Radiation Safety Manual, with training records on file with the RSO.

Personnel who perform the tasks described in this SOP must have the minimum following training or the equivalent associated refresher course within the previous 12 months, and the applicable documents to indicate their status:

- EPA Medical Monitoring
- HAZWOPER 40-Hr. Certification or an 8-Hr. HAZWOPER Refresher Course (as appropriate)
- Radiation Safety Training

In addition, First Aid/CPR certification w/ AED essential training via the American Red Cross or the American Heart Association must have been received within the previous 24 months.

4.1.3 Specific requirements are needed for personnel staffing surveying areas especially within a hotline. See SOP RPR-808 *Contamination Control Operations* for further qualifications.

4.2 PERSONNEL RESPONSIBILITIES

4.2.1 Personnel who perform the tasks described in this SOP must be aware of and comply with site specific requirements put forth in the site Health and Safety Plan (HASP) for the project or incident, and must follow ALARA principles, awareness of exposure and dose limits and turnback levels determined for the project.

4.2.2 All personnel who perform the tasks described in this SOP are responsible for following the procedures and quality assurance requirements described within this SOP and the CRPR QAM. All personnel must be aware of and comply with site specific regulations and QA protocols as defined by organizational management and/or the project Quality Assurance Project Plan (QAPP) or other environmental sampling plan.

4.2.3 Personnel who are involved in emergency response or other applications of radiation monitoring are responsible for assuring that instrumentation is maintained in a useable condition as outlined in the CRPR QAM.

4.2.4 Repairs or adjustments of settings that could affect how the instrument responds to radiation detection and measurements can only be performed by the Field Radiation Instrument Manager. It is the responsibility of the user to notify the Field Radiation Instrument Manager when an instrument is out of calibration, performance degrades, or damage has occurred.

4.2.5 Personnel who are involved in emergency response or other applications of radiation monitoring are responsible for the proper documentation of the surveys performed using protocols identified by the project planning documents. Proper documentation may include calibration data, source check records and instrument response characteristics, in addition to survey or monitoring logs or other data records. All records will be stored in the project file in accordance the CRPR QAM.

4.2.6 Any Field Monitoring Specialist surveying potentially contaminated personnel must take precautions to avoid getting the detector contaminated with radioactive materials. Examples of contamination control may include placing plastic onto areas when setting instruments down, wrapping instruments with plastic when possible, removing/reapplying gloves if contaminated.

5.0 EQUIPMENT AND SUPPLIES

- Portable Contamination Survey Instruments
- Clipboard
- Pencil/Pen
- Personnel and Clothing Contamination Report
- PPE as outlined in RPR-808, *Contamination Control Operations*
- Plastic sheeting/plastic wrap
- Cotton sheeting

6.0 REAGENTS AND STANDARDS

N/A

7.0 HEALTH AND SAFETY

7.1 Health Cautions

7.1.1 Field projects encompass a wide range of hazards. Take precautions while performing personnel monitoring, including the buddy system, line of site operations, and maintaining communication with others. The site HASP shall be reviewed and followed.

7.1.2 Personal Protective Equipment (PPE) and radiation dosimeters must be used during survey operations where contamination is known or suspected as required by the project HASP.

OPERATORS MUST ALWAYS WEAR THEIR RADIATION MONITORING BADGE (DOSIMETER) WHENEVER PERFORMING RADIOLOGICAL SURVEYS.

7.1.3 At a minimum, the Radiation Safety Manual (RSM), or site specific requirements as outlined in the QAPP and/or Health and Safety Plan (HASP), must be followed by all personnel in support of all field projects. All field personnel must practice ALARA principles at all times.

7.1.4 In the event that an injured person needs to receive lifesaving medical assistance, the person should be transported immediately to a medical facility. Priority must be given to lifesaving actions. Wrap the affected person in cotton sheeting to contain any external contamination as much as possible. Transport and hospital personnel will need to be aware of any potential contamination located on the victim to minimize contaminating transport vehicles and support facilities. Once the hospital equipped to handle radioactive contaminated patients is located, contact it at once to allow for radiation contamination control measures to be put in place.

7.1.5 Eating and drinking while surveying is prohibited. Personnel working in the survey area must be given the opportunity to take breaks in a clean area where food and water are available.

7.1.6 Report all injuries, accidents or near-misses to your immediate supervisor, and the SHEM or site Health and Safety Officer.

7.2 Equipment Cautions

In order to change some setting and the batteries on some portable survey meters, the meter will need to be opened exposing the internal electronics. Most radiation probes operate at ~900 volts, so caution should be exercised whenever opening or handling a meter with exposed electronics. This should never be done when the detector is "ON" due to the potential for electric shock. Additionally, care should be taken when handling the detector in an open configuration since there are many resistor/capacitor circuits within the detector which can store electrical charge after the detector is switched off.

8.0 SAMPLE COLLECTION, PRESERVATION, AND STORAGE

N/A

9.0 CALIBRATION AND STANDARDIZATION

All survey instruments shall meet RERT calibration requirements, including conformance to ANSI N323 or more stringent requirements, for use in an emergency response situation. These requirements include but are not limited to:

- Batteries must be tested
- Calibration documents must be available for all instruments.
- All survey instrument shall have been calibrated during the previous 12 months
- The instrument must meet routine daily quality control criteria.

Calibration and source check records shall be retained as required in the CRPR QAM.

10.0 PROCEDURE

10.1 Pre-requisite Actions for Survey Meters

10.1.1 Check the survey meter's battery by turning the meter knob to the battery test position. If the battery is adequately charged, the meter needle will swing to the battery test position on the meter face. Replace the batteries if the batteries are low.

10.1.2 Perform an operational check the first time the instrument is used each day or when you suspect the instrument may have been misused or damaged. Turn the meter on and turn the meter's scale switch to the lowest setting that will measure the check source and will provide a mid-scale reading but will not cause the needle to swing beyond full scale. Place the probe firmly against the check source and note the measurement in either a Daily Instrument QC Check Form, such as the FRMAC *Daily Instrument QC Check Form* located in Appendix 17.2, and/or a field logbook. If the observed meter response differs from the expected response by more than 20%, the meter should be considered nonfunctional and should be taken out of service.

10.1.3 Take the meter to an area away from sources of radiation and note the meter background reading. Background readings will vary due to location and the type of instrument. If the meter's background reading is substantially greater than expected, confirm that there are no unexpected sources of radiation or radioactive materials in the vicinity. Check with the Field Radiation Instrument Manager or equivalent to ensure that the meter is not contaminated.

10.1.4 For alpha or beta detection, do not cover the probe surface with parafilm, plastic, or other protective covering. Due to the low energy, the material may shield the meter from detecting contamination.

NOTE: Current EPA portal monitors are certified to detect 1 micro curie Cs-137. As a result, portal monitors will only detect gross contamination instances. If contamination is suspected, personnel should not be allowed to exit controlled area without performing a personnel frisk (as described below) by designated Field Monitoring Specialist.

10.2 Conducting a Whole-Body Frisk/Survey

The Field Monitoring Specialist will conduct whole-body frisks/scans with a pancake probe if looking for beta/gamma radiation, or an alpha/beta scintillator if looking for alpha/beta contamination.

10.2.1 Verify that the meter has power - if on battery power check the battery condition.

10.2.2 Verify that the range/decade selector switch is set to the times one scale depicted by the symbol "X1".

10.2.3 Verify that the radiation background will allow use of the meter (typically less than 150-200 cpm for pancake probes 1-2cpm for alpha scintillators).

10.2.4 Verify that the meter is set to "slow" response.

10.2.5 Verify the "audible" sound level is turned up so you can hear the "clicks".

10.2.6 When scanning, keep probe 1/4" to 1/2" from surface being scanned.

10.2.7 When scanning, move the probe slowly at a rate of 1 ½" to 2" per second.

10.2.8 If audible clicks are increasing, pause for a few seconds to allow for meter response time and check the meter for the reading.

10.2.9 When scanning, don't touch the item being scanned.

10.2.10 If the frisker alarms or has a large increase over background, re-set the meter and increase the scale switch and re-scan.

10.2.11 If there is a further alarm, or if you detect measurements that require decontamination, record the readings on the *Personnel and Clothing Contamination Report* located in Appendix 17.1. Place this form in a plastic bag, give to the contaminated individual and direct the individual to the area for decontamination.

10.3 Survey Order for Whole-Body Frisk

10.3.1 The appropriate method to use when scanning should start from the top of the persons head and work down to the person's feet. Special attention should be given to areas of the body that naturally form crevices, bend, spread contamination, or entry points into the body. A surveyor should refrain from surveying underneath areas where particles may fall onto the surveying instrument such areas include arms, hands, and feet. To prevent contamination onto the instrument, the Field Monitoring Specialist should ask the person to turn body parts so that contamination onto the instrument is avoided. A quick guidance of the order in which a person should scan is as follows:

1. Begin at head (pause at mouth and nose for approximately 5 seconds)
2. Neck and shoulders
3. Arms (pause at each elbow)
4. Chest and abdomen
5. Back, hips and seat of pants
6. Legs (pause at each knee)
7. Shoe tops
8. Shoe bottoms (pause at sole and heel)
9. The whole body frisk should take approximately 2 minutes.

10.4 Personnel Decontamination Survey

10.4.1 If radiation monitors (e.g., portal, hand-held count-rate instruments, perimeter alarms) alarm, indicating potential personnel contamination, a Field Monitoring Specialist or designee will conduct a whole body contamination survey on the contaminated individual to determine area(s) and level(s) of contamination as per section 10.2 and10.3.

10.4.2 If no contamination is detected, allow the individual to continue egress from the controlled area as per SOP RPR-808 *Contamination Control Operation.*

10.4.3 If contamination is detected, direct the individual to the designated decontamination area, e.g., the "decon-line". Perform all personnel decontamination in specified decontamination areas designated as specified by the site QAPP. Refer to SOP RPR-851 *Emergency Response Personnel Decontamination Procedure.*

10.4.4 Perform a final release survey. If all detectable contamination has been removed, release the individual from the controlled area as per SOP RPR-808 *Contamination Control Operation.* If contamination is still present, repeat steps in sections 10.2 and 10.3.

10.4.5 Depending on the location (e.g. nose, mouth, eyes, open wounds, etc.) of where contamination was found on personnel, an internal dosimetry evaluation and/or bioassay may be required. Notify the RSO if internal contamination is suspected.

11.0 QUALITY ASSURANCE

11.1 Quality Control

An operational check, including background checks, must be performed as specified in the site QAPP. At minimum, operational checks of both background and instrument stability must be performed at the beginning and end of use/shift for each location area. Background measurements are conducted away from contamination or QC sources. To conduct the instrument stability check, place the probe firmly against the check source. Results of both background (and location of background measurement) and the instrument stability check source results are noted in either a Daily Instrument QC Check Form, such as the FRMAC *Daily Instrument QC Check Form* located in Appendix 17.2, and/or a field logbook. Verify that both the background and the response to the check source are within 20% of the expected response.

11.2 Records Management

All records pertaining to environmentally related measurements and all documents relating to the Quality System must be archived, retained, and disposed of according to the requirements in the NCRFO QMP and the CRPR QAM.

11.2.1 Forms

All QC measurements including background checks and operational checks must be documented either by a Daily Instrument QC Check Form, such as the FRMAC *Daily Instrument QC Check Form* located in Appendix 17.2, and/or a field logbook as specified by CRPR QAM.

Contamination measurements will be documented on the *Personnel and Clothing Contamination Report* form located in Appendix 17.1.

11.2.2 Logbooks

Logbooks must be maintained according to the requirements described in the NCRFO QMP and CRPR QAM unless specific instruction is provided in project planning documents or specific project SOP. Logbooks are issued upon request by the QA Manager and once complete, are archived with the QA Manager.

11.3 Computer Hardware and Software Management

N/A—There are no specific requirements in place for the management of computer hardware or software associated with personnel monitoring for contamination.

11.4 Procurement Requirements

All procurements are made following the requirements in the Federal and EPA acquisition regulations as stated in NCRFO's QMP. The use of purchase cards for procurement must follow the NCRFO Purchase Card Policy.

11.5 Assessments

11.5.1 This SOP shall be reviewed at least once annually to assure that the procedures are appropriate and comprehensive.

11.5.2 The effectiveness of this procedure shall be evaluated at least annually by those personnel immediately responsible for overseeing and/or performing the tasks described by the procedure. Results of any review shall be used to improve the process and to revise this SOP and related quality documentation. Results shall also be documented per SOP RIE-101.

11.5.3 This document must reflect the quality requirements for all organizational parts of NCRFO. If changes to the organizational structure of NCRFO occur, this document must be reviewed and revised to reflect those changes.

11.6 Corrective Actions

If a procedural non-conformance is discovered or one occurs due to unforeseen circumstances, the non-conformance issue must be documented and corrective action process followed as defined in the CRPR QAM and NCRFO QMP.

12.0 DATA ANALYSIS AND CALCULATION

N/A

13.0 DATA REVIEW

Data obtained during the performance of this SOP must be reviewed as required by NCRFO data review policy found in NCRFO's QMP and the CRPR QAM.

14.0 METHOD PERFORMANCE

N/A

15.0 ENVIRONMENTAL MANAGEMENT SYSTEM

15.1 Pollution Prevention

N/A – This procedure does not generate any waste or materials that may pollute or cause pollution of the environment.

15.2 Waste Management

N/A – This procedure does not generate any waste or materials that may pollute or cause pollution of the environment.

16.0 REFERENCES

16.1 Specifications and Requirements

16.1.1 American National Standards Institute, *American National Standard Radiation Protection Instrumentation Test and Calibration, Portable Survey Instruments*, ANSI N323A-1997.

16.1.2 Radiation and Indoor Environments National Laboratory, *Standard Operating Procedure Development*, RIE-101 R6, August, 2012.

16.1.3 Radiation and Indoor Environments National Laboratory, *Quality Management Plan,* Revision 4, May, 2012 (also NCRFO QMP).

16.1.4 Radiation and Indoor Environments National Laboratory, *R&IE Purchase Card Internal Standard Operating Policy and Procedures*, May 2011 (also NCRFO Purchase Card Policy).

16.1.5 Radiation and Indoor Environments National Laboratory, *Radiation Safety Manual*, November 2012 (also NCRFO RSM).

16.1.6 Center for Radiation Preparedness and Response, *Quality Assurance Manual*, August 2013.

16.2 Guidance Documents or other special references

Federal Radiological Monitoring and Assessment Center, *Monitoring and Sampling Manual, Vol I and II*, DOE/NV/25946, July 2012

17.0 APPENDICES

Appendix 17.1 Personnel and Clothing Contamination Report
Appendix 17.2 Example of FRMAC Daily Instrument QC Checks Form

Appendix 17.1 Personnel and Clothing Contamination Report (Front)

PERSONNEL AND CLOTHING CONTAMINATION REPORT
(Page 1 of 2)

Contaminated Individuals Name:	Date:	Time:	IWP/Task #:
Project Name & Number:	Approx. surface area of contamination (cm^2):		Technician/Supervisor:
Approximate length of time that individual remained contaminated, including decontamination attempts:	Type of Contamination: ☐ Localized ☐ Discrete Particle ☐ Distributed		

Individual was wearing: ☐ Street Clothes ☐ Full Protective Clothing ☐ Lab Coat ☐ Scrubs

Probable Reason for Contamination (see attachment 1):

☐ Poor Work Practices	☐ Inadequate HP Controls	☐ Inadequate Protective Clothing
☐ Failure of Protective Clothing	☐ Contaminated PCs	☐ Perspiration Through PCs
☐ Planned Contamination	☐ Accidental Contamination	☐ Spread From Adjacent Work Area

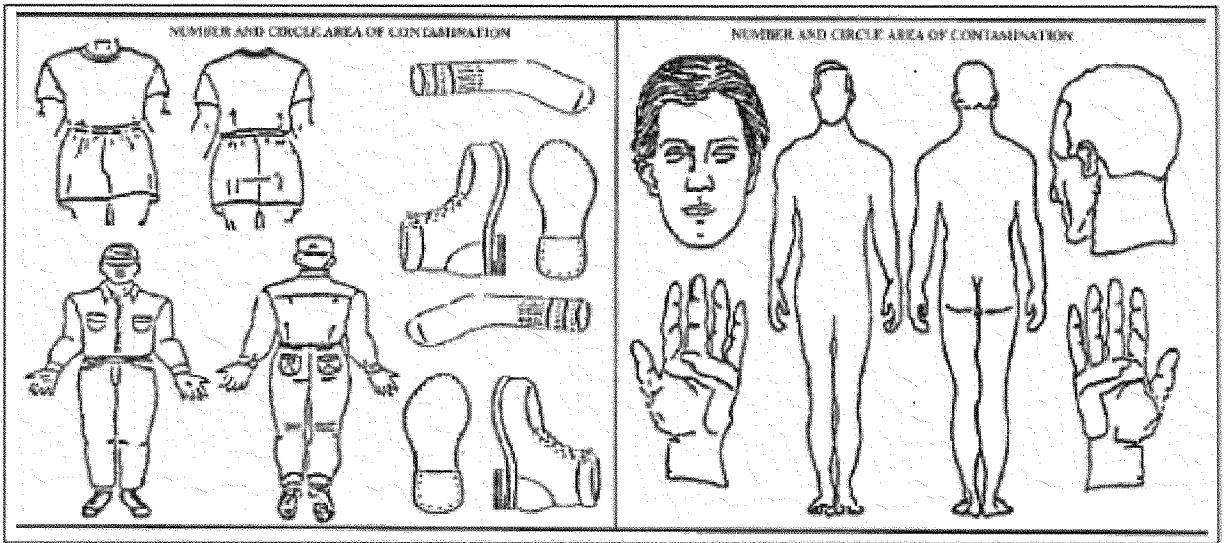
Comments:
Action Taken:

Appendix 17.1 Personnel and Clothing Contamination Report (Back)

PERSONNEL AND CLOTHING CONTAMINATION REPORT

(Page 2 of 2)

☐ CLOTHING CONTAMINATION ☐ SKIN CONTAMINATION



If a discrete particle is on clothing, provide survey through clothing, if possible.

Location No (mark on diagram)	cpm	1st Decon Method	1st Decon Results (cpm)	2nd Decon Method	2nd Decon Results (cpm)	3rd Decon Method	3rd Decon Results (cpm)

Instrument Type:	Serial No:	Cal Due Date:	Efficiency:	Background (cpm):
Instrument Type:	Serial No:	Cal Due Date:	Efficiency:	Background (cpm):

Disposition of clothing: _____

_____

_____

Surveyed by: _____
Print Sign Date Released

Reviewed by: _____
Print Sign Date

Form RPR850-001F, Rev.0, 03/12

Appendix 17.2 Example of FRMAC Daily Instrument QC Checks Form

DAILY INSTRUMENT QC CHECKS

Event _____ Team Name _____

Performed By _____ Reviewed By _____ Page _____ of _____

Instrument Serial Number	Instrument Model Number	Depart Date/Time DDMMMYYYY 0000 (Military)	QC Check Source Type	Check Source ID #	Check Source Activity	Acceptable Operating Range	Depart Actual Reading	Return Date/Time DDMMMYYYY 0000 (Military) [If Required]	Return Actual Reading [If Required]

October 2011

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	Revision 0	Effective Date 08/19/2013

Radiation Detection Instrument QC Checks

Responsible Official: Mark D. Sells Date: 5/30/2013

Technical Review: [signature] Date: 5/30/13
Technical Expert (Reviewer)

Approved By: Mark D. Sells Date: 5/30/2013
CRPR QA Coordinator

Approved By: [signature] Date: 5/30/2013
CRPR Center Director

Approved By: AB Date: 6/26/2013
NCRFO QA Manager

Approved By: [signature] Date: 6/20/2013
NCRFO Director

ANNUAL REVIEW

RO Review/Date: _____ Quality Review/Date: _____

RO Review/Date: _____ Quality Review/Date: _____

RO Review Date: _____ Quality Review/Date: _____

SOP REVISIONS

Rev. No.	Rev. Date	Revision	Responsible Official
0	May 30, 2013	Initial Issue	M. Sells

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1.0 PURPOSE

This SOP describes the procedures used to perform Quality Control (QC) checks on low exposure rate handheld radiation detection instruments. The QC checks described in this procedure are used to assure that radiation detection instrumentation maintained for emergency response activities or environmental programs will provide data of known quality and meet the requirements provided by the Center for Radiation Preparedness and Response (CRPR) Quality Assurance Manual (QAM) and the National Center for Radiation Field Operations (NCRFO) Quality Management Plan (QMP). This procedure is not intended for use as a field QC check procedure, but is an SOP for maintaining the instruments in readiness for use.

2.0 SCOPE AND APPLICABILITY

2.1 Scope, Application, Method Summary

NCRFO owns and maintains several hundred handheld radiation monitoring instruments of different models and types as a National Emergency Response Asset. The procedures provided in this SOP apply to the inventory of handheld radiation detection instruments owned and managed by NCRFO that are intended for low exposure rate measurement of alpha, beta, and gamma radiation. For this procedure, low exposure rate instruments are defined as that group of instruments that are primarily used to detect radiation from 0-20 mR/hr. Radioactive sources used for QC checks in this procedure will generally have an activity less than 5μCi.

The procedure details the process used to verify that the responses of the alpha and beta detectors are within QC limits, based on efficiencies generated for that instrument/detector combination using a prepared repeatable geometry and sources of known activity. The procedure also describes the process used to verify that the responses of the gamma radiation detection instruments are within QC limits, using a repeatable geometry by comparison to average response values determined from prior data from the same instrument type and configuration.

2.2 Interferences

2.2.1 Elevated gamma radiation background or the placement of beta/gamma sources within 3 meters of the source check area during measurements can cause interference in determining the instrument measurement response.

2.2.2 Crosstalk can occur between channels on α/β discriminator instruments. The operator must take instrument crosstalk into account when using sources that emit both alpha and beta particles.

2.3 Potential Problems

QC checks of instrument efficiency use QC limits of ±20% based on the efficiencies listed in the calibration certificate provided by the instrument calibration vendor for comparison. It is important to verify that the source radionuclide and the calibration geometry (typically the distance from the face of the source to the face of the detector) listed on the instrument calibration certificate are the same as used for the QC check.

3.0 DEFINITIONS

3.1	ALARA	As Low As Reasonably Achievable
3.2	CPM	Counts per Minute
3.3	Crosstalk	Detection of particulate radiation in the improper channel (alpha in beta channel, or beta in alpha channel)
3.4	DPM	Disintegrations per Minute
3.5	Efficiency	Ratio of counts to disintegrations, expressed as a percentage
3.6	GM	Geiger Muller, class of gas filled radiation detectors
3.7	QC	Quality Control
3.8	RSO	Radiation Safety Officer
3.9	SGB	Source Geometry Board
3.10	SYS#	(also SYSTEM#) Tracking/Identification number used for Serial-number specific instrument or instrument/detector combinations

4.0 PERSONNEL

4.1 PERSONNEL QUALIFICATIONS

4.1.1 Personnel who perform radiation instrument QC checks must be provided with training, followed by a demonstration of proficiency in the procedure. If training courses are not available, personnel will learn to perform this procedure under the direct supervision of a subject matter expert. Training and demonstrations of proficiency must be performed and documented in accordance with the Center for Radiation Preparedness and Response (CRPR) Quality Assurance Manual and must be consistent with the National Center for Radiation Field Operations (NCRFO) Quality Management Plan (QMP, also R&IENL QMP).

4.1.2 Personnel who perform radiation instrument QC checks described in this SOP must have received radiation safety training within a 12-month period as specified in the Radiation Safety Manual, with training records on file with the RSO.

4.2 PERSONNEL RESPONSIBILITIES

4.2.1 Personnel using the procedures and instrumentation described in this SOP are responsible for consideration of any safety issues or requirements involved with the handling, transportation or storage of radiation check sources.

4.2.2 Personnel who perform radiation instrument QC checks are required to fully document the checks using QC Check Form RPR440-001F (example Appendix 17.1) or equivalent, and to obtain a quality reviewer signature on all QC Check Forms generated using this procedure. The reviewer must be a person who is familiar with the instrument and the QC check procedure.

4.2.3 Personnel who perform radiation instrument QC checks are responsible for the proper archival of the QC Check Forms in the QC check binder located in the NCRFO instrument shop facility.

4.2.4 The Field Radiation Instrument Manager, also referred to in this SOP as the Instrument Manager, is responsible for the management of the CRPR instrument inventory including maintenance of instruments, calibration, records management, quality assurance and procedure development for the use and operation of the instruments.

5.0 EQUIPMENT AND SUPPLIES

5.1 CRPR Instrument QC Check Geometry Board with contact shim (see Figure 1)

5.2 CRPR Instrument QC Check Source kit Containing:

- Source C4-054, 0.05029 μCi ^{90}Sr/Y, 3/15/2005, or certified equivalent
- Source C4-025, 0.05629 μCi ^{239}Pu, 3/1/2005, or certified equivalent
- Source C4-070, 0.06 μCi ^{230}Th, 3/1/2005, or certified equivalent
- Source RS-2279, 1 μCi ^{137}Cs, or equivalent 0.5 - 2 μCi source
- Source RS-94040, 5 μCi ^{137}Cs, or equivalent 3-8 μCi source

5.3 CRPR QC Check Form (RPR440-001F, example Appendix 17.1), used to record individual QC results (one form used each time a QC check is performed).

5.4 CRPR Source Evaluation Form (RPR440-002F, example Appendix 17.2) used to track specific sources and the responses of different instrument/detector combinations to different sources. A separate form is used for each source and instrument/detector combination.

5.5 Calibration Source Information Sheet (example Appendix 17.3), used as a reference for the activity of each source and the ±20% values used as QC limits for efficiency verification. Instrument and detector-specific QC limits are added to the Information Sheet as they are established.

6.0 REAGENTS AND STANDARDS

6.1 QA sources used to determine the efficiency of the detectors or the accuracy of the system must have a NIST traceable certificate of calibration that contains the following information:

- Source Identification or reference number
- Radionuclide
- Radionuclide activity
- Reference date of activity determination
- Stated reference activity with less than 5% uncertainty at the 95% confidence level

6.2 Check sources used for functional checks or to determine repeatability and response characteristics do not require as stringent an assay of activity. These sources can be used for routine or daily QC checks. The response characteristics of unique instrument/detector configurations are tracked for statistical analysis of response over time to determine acceptance limits for each configuration and source.

7.0 HEALTH AND SAFETY

7.1 Health Cautions

7.1.1 Personnel must always be aware that some types of sources used for QC checks may have removable radioactive material present. Plated and paper sources have fixed radionuclides but can be damaged by improper handling. Always handle sources from the edges and never scrape or rub the plated or active surfaces. Never place tape or any other adhesive on the active surface of the source.

7.1.2 Personnel must always consider ALARA procedures when handling radiation sources. Always remove sources from the QC check area when not being used so that they will not interfere with the current check.

7.2 Equipment Cautions

Always be aware that radiation detection instruments have high voltage output to detectors and internal high voltage points often exceeding 900V. Verify that instruments are turned off when attaching/disconnecting cables/detectors or whenever the instrument body is opened. Instrument circuits often use capacitors that store charge so care should be taken when handling instruments even when they are turned off and batteries have been removed.

8.0 SAMPLE COLLECTION, PRESERVATION, AND STORAGE

N/A

9.0 CALIBRATION AND STANDARDIZATION

9.1 All survey instruments shall meet RERT calibration requirements, including conformance to ANSI N323 or more stringent requirements, for use in an emergency response situation. These requirements include but are not limited to:

- Batteries must be tested
- Calibration documents must be available for all instruments.
- All survey instrument shall have been calibrated during the previous 12 months
- The instrument must meet routine daily quality control criteria when in use.

9.2 Sources used for the determination of efficiency must have a certificate of calibration that includes the source assay of activity and the associated reference date and if applicable, the 2π particle emission rate of the source for alpha and/or beta radiation.

9.3 Calibration and source check records shall be retained as required in the CRPR QAM

10.0 PROCEDURE

10.1 Prepare new QC Check Form for each instrument to be Quality Checked.

10.1.1 Use form RPR404-001F, Instrument QC Check Form (see example Appendix 17.1).

10.1.2 Complete the top section of the form with the appropriate instrument and detector data.

10.1.3 Complete the "SOURCE Information" section of the form with the appropriate information about the specific sources used for this QC check. Determine today's activity from the table provided in the Check Source Information Sheet provided by the Instrument Manager (see example Appendix 17.3) using the value for the month when adjusting the strontium source and the yearly decay information for the Cesium, Plutonium and Thorium sources.

- Use Source C4-025, 0.05 µCi ^{239}Pu for Alpha efficiency checks
- Use Source C4-054, 0.05 µCi ^{90}Sr/^{90}Y for Beta efficiency checks
- Use Source C4-070, 0.06 µCi ^{230}Th for determination of ^{230}Th efficiency
- Use Source RS-8049, 1 µCi ^{137}Cs and Source RS-94040, 5 µCi sealed button sources for gamma response checks

For checks using alpha and beta sources, record the acceptance range in dpm as indicated on the Source Information Sheet on the QC Check Form as "acceptable range" For checks using gamma sources, efficiencies are inappropriate, and simple response checks are used to track instrument stability over time. Enter the typical range for gamma QC check response from Appendix 17.3.

10.2 Perform Instrument Physical Check

10.2.1 Check the calibration sticker on the instrument. If the calibration due date has passed, return the instrument to the Instrument Manager. Verify that the calibration sticker information accurately represents the calibration certificate information.

10.2.2 Examine the instrument for obvious physical damage. Look for damage to switches or knobs, proper meter dial function, meter zero and battery corrosion.

10.2.3 Examine the instrument cable when an external detector is used. Verify that the cable is not pinched, cut or damaged and the connectors are in good condition.

10.2.4 Turn the instrument on and perform an instrument battery check. Replace weak or dead batteries.

10.2.5 Test the instrument audio function.

10.2.6 Allow at least five minutes for the instrument to warm up.

10.2.7 Complete the Instrument Physical Check portion of the QC Check Form. If the instrument or cable is damaged or the instrument does not function properly, remove the instrument from service and immediately notify the Instrument Manager for repair or replacement.

10.3 Determine type of source check required.

Refer to Table 1 (below) to determine the appropriate type of source to use for the instrument or detector. Contamination survey meters (alpha/beta) require an efficiency check while exposure rate meters (gamma, plus ion chambers with beta window) require only a source response check.

Table 1 – Source Check vs. Detector Type

Instrument Type	Detector Type	Type of Check Needed
Exposure/Dose Rate Meter Ex. Ludlum 19 MicroR, MicroRem	Internal Only (NaI scintillation detector)	Gamma Response only
Exposure Rate Meter Ex. Eberline RO-2A, Ludlum Model 17	Internal Only w/ Beta Window (Ion Chamber)	Gamma (window closed) and Beta (window open) Response Check
Exposure Rate Meter Ex. Ludlum 14C, Eberline E-520	External GM w/shield (Hotdog 44-6 or 44-38 or HP-270)	Open and Closed shield Gamma and Beta, Response check only
Count Rate Meter Ex. Ludlum Model 3/3A/12/101	External GM (Pancake 44-9, HP-260 or similar)	Beta efficiency check Alpha efficiency check optional
Count Rate Meter Ex. Ludlum Model 3/3A/12/101	External Alpha Scintillation Detector (Ludlum 43-90 or similar)	Alpha Efficiency Check
Count Rate Meter w/ Alpha-Beta discriminator Ex. Ludlum Model 2224, 2360	External Alpha/Beta Scintillation Detector (Ludlum 43-89, 43-93 or similar)	Alpha Efficiency Check Beta Efficiency Check Determination of Crosstalk

10.4 Prepare Source Geometry Board

A 'Source Geometry Board' (SGB) is used in this procedure to establish and maintain a repeatable geometry (positioning) for source checks of instruments and detectors (see Figure 1).

The SGB allows consistent checks to be performed on most instrument and detector models used by the RERT and NCRFO. The SGB holds the source in place and the instrument or detector placements are marked on the board for consistent positioning. The sources are placed into recessed areas of the board at the appropriate depth to maintain one centimeter (1 cm.) of distance between the source and the detector face, which is the same geometry listed on the calibration certificate issued after each calibration. In some cases the detector efficiency is listed as contact efficiency for the detector. A special shim is supplied to elevate the source so the face of the detector is in contact with the source to achieve this geometry.

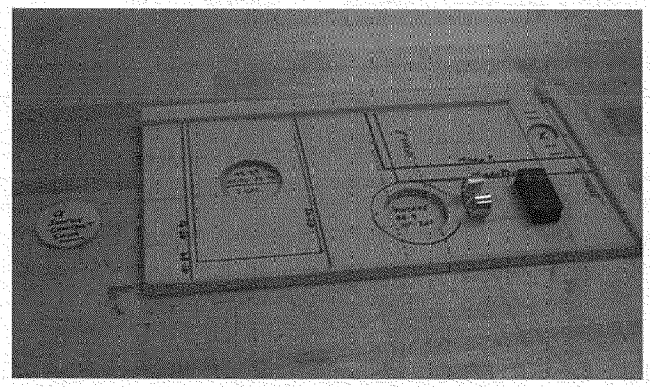

Figure 1: Source Geometry Board

10.4.1 Verify the source geometry specified on the instrument Calibration Certificate and the calibration sticker used to determine the detector efficiency. Annotate the geometry to be used (contact or 1 cm.) in the "Instrument Source Checks" section of the QC Check formUse the contact shim provided if contact geometry is listed as the source efficiency distance.

10.4.2 Assure that the geometry board is isolated from other sources of radiation that could interfere with QC checks or background measurements.

10.4.3 The Source Geometry Board is kept in the NCRFO instrument shop (room LaPlaza C-538). The sources used for the QC checks are maintained as a specific kit for use with the SGB, and are labeled and stored in the source storage cabinet in room LaPlaza C-528.

10.4.4 Use only one source at a time when performing QC checks. Keep the other sources from the QC check kit segregated from the area where checks are being performed to prevent interference with the check being done.

10.4.5 Use the appropriate marked areas based on the detector type for QC checks. Use the rightmost position for gamma response-only checks. Use the leftmost source position on the board for alpha scintillation or phoswich detectors where individual detector types are outlined. Use the center position for Pancake detectors. Always record the detector geometry (Contact or 1 Cm.) on the QC Check Form for efficiency determinations.

NOTE: This is important because the depressions in the SGB are the appropriate depth for each type of detector to maintain 1 centimeter of distance between the detector face and the source.

10.5 Low exposure rate gamma instrument response check

Gamma response checks are to be used for exposure rate instruments designed for gamma or beta/gamma detection. This includes low exposure rate instruments such as the Ludlum Model 19 MicroR meter or the Bicron MicroRem meters with an internal scintillation detector.

10.5.1 Before removing the check source from the kit, determine the instrument background by placing the instrument in position on the SGB and setting it to the lowest range. Allow the instrument to fully stabilize using the slow response mode prior to reading and recording the meter response.

10.5.2 Place the 1 μCi Cesium source (RS-8049) into the SGB at the marked γ location.

10.5.3 Place the meter into the SGB in the marked area or so the instrument detector is placed directly over the center of the source.

10.5.4 Place the instrument response switch to slow response mode.

10.5.5 Allow the reading to stabilize for 20 seconds to one minute.

10.5.6 Determine the instrument "Source Reading + units" and record on the QC Check Form.

10.5.7 Determine the "Net Reading + units" by subtracting the background value from the source reading and record on QC Check Form.

10.5.8 Repeat the response check process using the 5 μCi Cesium source (RS-94040) using the original background value and recording the response on the next line of the form.

10.5.9 Compare the "Net Reading" determined for each source against the acceptance range noted on the QC Check Form.

Note: The default response check values in Table 2 are general values based on ANSI N323 (+-20%). Specific values for each SYSTEM# are determined by the Instrument Manager through the analysis of previous check source data for each instrument/detector configuratio as documented in the Source Evaluation Form, Appendix 17.2.

10.5.10 If the response is in the appropriate range, mark the instrument as "pass" on the QC Check Form and proceed with any other checks required for that instrument.

10.5.11 If the response is outside of the appropriate range, mark the instrument as "fail" on the QC Check Form and repeat the response check. The instrument must pass the check two times in a row after a failure, or the instrument does not pass the QC check. If the instrument does not pass the QC check, notify the Instrument Manager for further action and remove the instrument from service.

10.6 Hotdog GM detector beta/gamma response check

Hotdog GM detectors should be evaluated for each radiation type (beta and gamma) with both shield-open and shield-closed configuration. This includes medium range (0-2 R/hr.) instruments with external GM detectors such as Ludlum Model 14C with a Ludlum 44-38 or 44-6 hotdog style detector.

10.6.1 Before removing the check source from the kit, determine the instrument background by placing the instrument in position on the SGB and setting it to the lowest range. Allow the instrument to fully stabilize using the slow response mode prior to reading and recording the meter response.

10.6.2 Place the 5 μCi Cesium source (RS-94040) into the gamma source (rightmost) position on the SGB.

10.6.3 Starting with the shield closed, place the detector on the SGB in the outlined area so the detector shield window area is placed directly over the center of the source.

10.6.4 Place the instrument response switch to slow response mode and allow the reading to stabilize for 20 seconds to one minute.

10.6.5 Determine the instrument "Source Reading + units" and record the value on the QC Check Form.

10.6.6 Determine the "Net Reading + units" by subtracting the background value from the source reading and record on QC Check Form.

10.6.7 Repeat this measurement with the shield open and record it on a separate line on the QC Check Form.

10.6.8 Remove the Cesium source from the SGB and place the ^{90}Sr/Y source (RS C4-054) into the receptacle used for pancake efficiency determination (center position).

10.6.9 Repeat steps 10.6.3 through 10.6.7 using the ^{90}Sr/Y source (RS C4-054) in the center position on the SGB.

10.6.10 Compare the activity values determined in the above response checks against the acceptance range noted on the QC Check Form as obtained from Table 2.

10.6.11 If the response is in the acceptable range, mark the detector as "pass" on the QC Check Form and proceed with any other checks required for that detector.

10.6.12 If the response is outside of the acceptable range, mark the detector as "fail" on the QC Check Form and repeat the efficiency check. The instrument must pass the check two times in a row after a failure, or the detector does not pass the QC check. If the detector does not pass the QC check, notify the Instrument Manager for further action and to remove the instrument from service.

10.7 Alpha/Beta Scintillation detector efficiency check

Efficiency checks are required for ZnS(Ag) or phoswich scintillation detectors used for alpha or alpha/beta detection. Generally, scintillation detectors are matched to a standard count-rate meter and phoswich type detectors are used with a ratemeter or datalogger with an alpha-beta discriminator. This type of detector is usually a large area detector (up to 150 cm^2) but can also be a smaller end-window type detector.

10.7.1 Verify the detector efficiency and geometry listed on the instrument calibration certificate.

10.7.2 Before removing the check source from the kit, determine the instrument background by placing the detector in position on the SGB, setting the instrument to the lowest range. Allow the instrument to fully stabilize using the slow response mode for count rate meters prior to reading and recording the meter response. If the instrument has scaler capability, count the source for one full minute to determine the count rate (cpm).

10.7.3 Record background and units on the QC Check Form.

10.7.4 Select the appropriate source. For alpha efficiency, use the ^{239}Pu source RS C4-025 and for beta use the $^{90}Sr/Y$ source RS C4-054. For α/β discriminators, perform both checks using separate lines on the QC Check Form.

10.7.5 Place the source into the leftmost position on the SGB. If contact geometry is required, place the contact geometry shim into the depression under the source.

10.7.6 Place the detector in position centered over the source. Repeatable positions are marked for Ludlum 43-89/43-90 and 43-93 detectors. For other detector types, position the center of the detector over the center of the source as closely as possible.

10.7.7 Allow the instrument to fully stabilize using the slow response mode for count rate meters prior to reading and recording the meter response. If the instrument has scaler capability, count the source for one full minute to determine the count rate (cpm).

10.7.8 Complete the line on the QC Check Form by determining and recording the net count rate in cpm for the source by subtracting the background value determined in step 10.7.2 from the instrument's response to the source.

10.7.9 Determine the source activity in dpm by dividing the result (cpm) by the efficiency provided on the instrument calibration certificate and record the value (dpm).

10.7.10 Compare the activity value determined against the acceptable range for the source as completed previously on the QC Check Form in the Source Information section.

10.7.11 If the response is in the acceptable range, mark the detector as "pass" on the QC Check Form.

10.7.12 If the response is outside of the acceptable range, mark the detector as "fail" on the QC Check Form and repeat the efficiency check. The instrument must pass the check two times in a row after a failure, or the detector does not pass the QC check. If the detector does not pass the QC check, notify the Instrument Manager for further action and remove the instrument from service.

10.7.13 Upon completion of the efficiency QC check using the 239Pu and 90Sr/Y sources, determine the detector's alpha efficiency to ^{230}Th using source C4-070 at 1 cm.

- Determine the net (source – bkgd.) instrument response to the ^{230}Th source in cpm.
- Divide the instrument response (cpm) by the source activity in dpm found on the Calibration Source Information Sheet to obtain the efficiency to the thorium source.

Record the calculated ^{230}Th efficiency in the Comments section of the QC Check Form and on the Instrument Calibration Certificate.

10.7.14 Determine the crosstalk for those instruments that have the capability to discriminate between alpha and beta (dual channel instruments, for example Ludlum 2360 with a 43-90 detector).

- Determine the net instrument response to alpha and beta sources for both alpha and beta channels.
- Use the equations in section 12.2 of this SOP to determine the crosstalk.
- Record crosstalk calculations in the Instrument Response Tracking Form.

Acceptable crosstalk values are < 1% beta in alpha channel and < 10% alpha in beta channel crosstalk.

10.8 Pancake GM efficiency determination

10.8.1 Verify the detector efficiency to the source being used, and the distance (geometry) listed on the instrument's calibration certificate.

10.8.2 Before removing the check source from the kit, determine the instrument background by placing the detector in position on the SGB, setting the instrument to the lowest range. Allow the instrument to fully stabilize using the slow response mode for count rate meters prior to reading and recording the meter response. If the instrument has scaler capability, count the source for one full minute to determine the count rate (cpm).

10.8.3 Select the appropriate source type (alpha/beta). For alpha efficiency, use the ^{239}Pu source RS C4-025 and for beta use the ^{90}Sr/Y source RS C4-054.

10.8.4 Place the source into the center position on the SGB. If contact efficiency is needed, place the contact shim into the depression under the source.

10.8.5 Place the detector in position centered over the source. A clip is positioned to hold the pancake detector in place over the source in a repeatable geometry.

10.8.6 Allow the instrument to fully stabilize using the slow response mode for count rate meters prior to recording the meter "Source Reading + units (cpm)" on the QC Check Form. If the instrument has scaler capability, count the source for one full minute to determine the count rate.

10.8.7 Complete the line on the QC Check Form by determining and recording the "Net Reading + units (cpm)" for the source by subtracting the background value determined in step 10.8.2 from the source reading.

10.8.8 Determine the source activity in dpm by dividing the result by the efficiency provided on the instrument calibration sheet and record the value in the "Result/Eff." column.

10.8.9 Compare this activity value against the acceptable range for the source as previously completed on the QC Check Form in the Source Information section.

10.8.10 If the response is in the acceptable range, mark the detector as "pass" on the QC Check Form and proceed with any other checks required for that detector.

10.8.11 If the response is outside of the acceptable range, mark the detector as "fail" on the QC Check Form and repeat the efficiency check. The instrument must pass the check two times in a row after a failure, or the detector does not pass the QC check. If the detector does not pass the QC check, notify the Instrument Manager for further action and remove the instrument from service.

10.8.12 Upon completion of the efficiency QC check, determine the detector alpha efficiency for ^{230}Th using source C4-070 at one cm.

- Determine the instrument response to the ^{230}Th source in cpm.
- Divide the instrument response (cpm) by the source activity in dpm found on the Calibration Source Information Sheet.

Record the results in the comments section of the QC Check Form and the instrument calibration certificate with this efficiency.

10.9 Response Criteria

Response criteria for QC checks are shown in Table 2 below.

TABLE 2, Quality Control Check Acceptance limits

Detector Type	Source Type	Tolerance
Frisker (contamination survey) GM, cpm	Strontium/Yttrium-90, Plutonium-239	Bkgd. – Typical < 80 cpm Eff. ± 20% of calibrated eff.
Frisker (contamination survey), Scintillation, cpm	Cesium-137	Bkgd. – Depending on Type Source ± 20% of calculated source activity
Exposure rate GM, µR/hr, mR/hr	Cesium-137	Bkgd. – Typical 2-15 µR/hr Source - ± 20% of the mean response by type
Exposure rate, Scintillation, µR/hr	Cesium-137	Bkgd. – Typical 2-15 µR/hr Source - ± 20% of the mean response by type

Note: The tolerances listed in Table 2 are default values based on the +-20% limits suggested by ANSI N323. As responses to specific sources are tracked over time, individualized QC limits will be developed and added to the Instrument Tracking Form.

10.10 Complete and archive the Instrument QC Check Form.

10.10.1 Complete the Instrument Quality Check Form by signing the form in the signature area at the bottom of the form after verifying that all of the data entered on the form is complete and correct.

10.10.2 Submit the completed form to the CRPR QA Coordinator or the CRPR Instrument Manager or a designated QC reviewer for review and signature.

10.10.3 Place the signed form into the appropriate order by system number in the CRPR QC Check Instrument storage folder for archive.

11.0 QUALITY ASSURANCE

11.1 Quality Control

11.1.1 Instrument Quality Control checks will be performed every time an instrument is removed from its storage location for use on any projects that involve the collection of environmental data or data for personnel protection.

11.1.2 If the instrument fails a pre-operational check, or if the instrument background falls outside of the acceptance criteria found in section 10.9, the instrument will be removed from service immediately for evaluation by the Instrument Manager.

11.1.3 The instrument can be used if the calculated efficiency or response is within the QC limits specified for that instrument type, or instrument/detector combination, source type, and geometry.

11.1.4 Instruments capable of alpha-beta discrimination must be rejected if the system crosstalk exceeds the manufacturer specifications or $\leq 10\%$ alpha in beta channel, and $\leq 1\%$ beta in alpha channel.

11.1.5 Acceptance criteria for response-only QC checks are determined by tracking the response to each source for each instrument/detector configuration. As data becomes available through QC checks for each specific instrument/detector configuration, a mean response value and QC limits are determined for that instrument/detector configuration for each specific source. As additional data are acquired for each instrument/detector and source configuration, the data will be appended to the original data and the mean response values will be updated and recorded on the Source Information Sheet (Appendix 17.3).

11.2 Records Management

All records pertaining to environmentally related measurements and all documents relating to the Quality System must be archived, retained, and disposed of according to the requirements in the NCRFO QMP and the CRPR QAM.

11.2.1 Instrument QC Check Forms shall be maintained in a three-ring binder (QC Check binder) on a calendar year basis. All original forms are to be inserted into the QC Check binder in sequence by the CRPR system number for the instrument.

11.2.2 Calibration Source Information Sheets with source decay and response criteria are generated by the Instrument Manager prior to the performance of QC checks. Copies of the Calibration Source Information shall be maintained in the front section of the QC Check binder.

11.2.3 The calculations made from existing QC check data to determine specific instrument/detector response criteria shall be documented using a spreadsheet or appropriate form to track the response data. Form RPR440-002F, Source Evaluation Sheet (see example, Appendix 17.2) or equivalent shall be used to track instrument response data. The documentation shall be maintained in the front section of the QC Check binder.

11.2.4 The QC Check binder is to be kept and maintained in the NCRFO instrument shop, LaPlaza Building C, Room 538. Separate binders shall be created for each calendar year. QC Check binders will be clearly labeled and kept indefinitely.

11.3 Computer Hardware and Software Management

N/A

11.4 Procurement Requirements

N/A

11.5 Assessments

11.5.1 This SOP shall be reviewed at least once annually to assure that the procedures are appropriate and comprehensive.

11.5.2 The effectiveness of this procedure shall be evaluated at least annually by those personnel immediately responsible for overseeing and/or performing the tasks described by the procedure. Results of any review shall be used to improve the process and to revise this SOP and related quality documentation. Results shall also be documented per SOP RIE-101.

11.5.3 This document must reflect the quality requirements for all organizational parts of NCRFO. If changes to the organizational structure of NCRFO occur, this document must be reviewed and revised to reflect those changes.

11.6 Corrective Quality Actions

If a procedural non-conformance is discovered or one occurs due to unforeseen circumstances, the non-conformance issue must be documented and corrective action process followed as defined in the CRPR QAM and NCRFO QMP.

12.0 DATA ANALYSIS AND CALCULATION

12.1 Detector Efficiency (performed for each channel/source type)

Note: The activity of the source used for this determination must be certified and decayed to the current date and time for accuracy.

$$\%Eff_{source} = \left(\frac{CPM_{Source} - CPM_{Bkgd}}{DPM_{Source}}\right) 100 \qquad \text{Eq. 1}$$

Where CPM_{Source} = Counts per minute of the source

CPM_{Bkgd} = Counts per minute of the background count

DPM_{Source} = Known emission rate of the source in disintegrations per minute

12.2 Crosstalk Calculations, performed for each channel

12.2.1 Beta in Alpha channel crosstalk will occur when beta radiation is present and a portion of the beta pulses are detected in the alpha channel and show up as alpha counts. This value should be ≤ 1% but may indicate the presence of alpha particles when there are none.

$$C_{Beta} = \left(\frac{Counts\ in\ Alpha\ Channel}{Counts\ in\ Beta\ Channel}\right) \times 100 \qquad \text{Eq. 2}$$

Where C_{Beta} = % Beta Crosstalk

12.2.2 Alpha in beta channel crosstalk will occur when alpha radiation is present and a portion of the alpha pulses are detected in the beta channel and show up as beta counts. This value should be ≤ 10% but may indicate the presence of beta particles when there are none.

$$C_{Alpha} = \left(\frac{Counts\ in\ Beta\ Channel}{Counts\ in\ Alpha\ Channel}\right) \times 100 \qquad \text{Eq. 3}$$

Where C_{Alpha} = % Alpha Crosstalk

13.0 DATA REVIEW

Data obtained during the performance of this SOP must be reviewed as required by NCRFO data review policy found in NCRFO's QMP and the CRPR QAM.

13.1 The technician/operator that performs the instrument QC check shall review each QC Check Form for completeness and correct data upon completion of the check. The initial review should be done to assure that the appropriate instrument and detector system number and serial numbers are correct and that measurement units and response criteria are recorded correctly. The operator must sign and date the form upon completion and submit the form for review to a qualified designated QC reviewer.

13.2 A designated QC reviewer shall review the QC Check Form for completeness, comparability, representativeness and accuracy and to verify that the instrument response is within specified limits and is approved for use by RERT and NCRFO personnel. The reviewer shall also assure that the forms are placed appropriately into the CRPR QC Check document storage binder for archive.

14.0 METHOD PERFORMANCE

N/A

15.0 ENVIRONMENTAL MANAGEMENT SYSTEM

15.1 Pollution Prevention

N/A – This procedure does not generate any waste or materials that may pollute or cause pollution of the environment.

15.2 Waste Management

N/A – This procedure does not generate any waste or materials that may pollute or cause pollution of the environment.

16.0 REFERENCES

16.1 Specifications and Requirements

16.1.1 Radiation and Indoor Environments National Laboratory, *"Standard Operating Procedure Development,"* RIE-101 R6, August 2012

16.1.2 Radiation and Indoor Environments National Laboratory, *"Quality Management Plan,"* Revision 4, May 2012 (also NCRFO QMP)

16.1.3 Radiation and Indoor Environments National Laboratory, *"Radiation Safety Manual,"* November 2012

16.1.4 Center for Radiation Preparedness and Response, *"Quality Assurance Manual,"* August 2013

16.1.5 American National Standards Institute, *"American National Standard Radiation Protection Instrumentation Test and Calibration, Portable Survey Instruments,"* ANSI N323A-1997

16.1.6 American National Standards Institute, *"Installed Radiation Protection Instrumentation Test and Calibration - Portable Survey Instruments for Near Background Operation,"* ANSI N323B-2003

16.2 Guidance Documents or other special references

Ludlum Measurements, Inc., *"Detection Sensitivity and MDA (Parts 1 and 2)"*, Ludlum Report, Volume 13, Number 1, December 1998 and Volume 14, Number 1, March 1999

17.0 APPENDICIES

17.1 Example Instrument QC Check Form RPR440-001F

17.2 Example Source Evaluation Form RPR440-002F

17.3 Example Calibration Source Information Sheet

Appendix 17.1, Example, Instrument QC Check Form, RPR440-001F

CRPR Instrument Quality Check Form

Operator	Today's Date	
Instrument/Detector SYSTEM #		
Inst. Make/Model:	Det. Make/Model	Eff. α
Inst. Serial #	Det. Serial#	Eff. β

SOURCE Information

Alpha Source I.D._____ Isotope:_____
Mfg. date _____ Activity_____
Current Activity_____
Acceptable Range _____to_____

Beta Source I.D._____ Isotope:_____
Mfg. date _____ Activity_____
Current Activity_____
Acceptable Range _____to_____

Gamma Source I.D._____ Isotope_____ Mfg. date _____
Current Activity _____ Typical Range (contact) _____to_____

Instrument Physical Check

Instrument Condition	◯ like new	◯ Some wear and tear	◯ Obvious damage
Battery Check	◯ Good	◯ Batteries Replaced	
Cable Condition	◯ O.K	◯ Damaged/Replaced	◯ N/A
Audio Check	◯ O.K.	◯ Fail	

Instrument Source Checks

#	Geometry	α/ß/γ	Background +Units	Source Reading + units	Net Reading + units	Result Eff.	Comments/ Pass-Fail
1							
2							
3							
4							
5							

COMMENTS/REPAIRS:_____

Signature_____ Date_____ QC Check by _____ Date _____

FORM RPR440-001F Rev. 2, May. 2013

Appendix 17.2, Example, Source Evaluation Form, RPR440-002F

Source Evaluation Record

Source I.D.__________________________

Date	SYS#	Model	Detector	BKGD	Source	NET	Eff.	Activity

Form RPR440-002F, Rev. 1, Mar 2013

Appendix 17.3, Example Calibration Source Information Sheet, front

2013 CERMER CALIBRATION SOURCE INFORMATION SHEET

BETA Source C4-054, ^{90}Sr

Original activity = 0.05029 µCi = 111,644 β/min on 3/15/2005

Certified Emission rate = 131,400 β/min (2π) OR **262,800 β/min (4π) on 2/25/2005 (^{90}Sr+Y)**

DATE	*ACTIVITY (µCi)*	*ACTIVITY (dpm 4π)*	*ACCEPTANCE RANGE Dpm 4π*
Jan 1, 2013	0.04168	217,541	174,032 – 261,049
Feb 1, 2013	0.04159	217,096	173,677 – 260,516
March 1, 2013	0.04152	216,696	173,357 – 260,035
April 1, 2013	0.04143	216,254	173,003 – 259,504
May 1, 2013	0.04135	215,826	172,661 – 258,992
June 1, 2013	0.04127	215,386	172,309 – 258,463
July 1, 2013	0.04118	214,960	171,968 – 257,952
Aug. 1, 2013	0.04110	214,521	171,617 – 257,426
Sept. 1, 2013	0.04102	214,083	171,267 – 256,900
Oct. 1, 2013	0.04094	213,660	170,928 – 256,392
Nov. 1, 2013	0.04085	213,224	170,579 – 255,869
Dec. 1, 2013	0.04077	212,803	170,242 – 255,363
Jan. 1, 2014	0.04069	212,368	169,895 – 254,842

ALPHA Source C4-025, ^{239}Pu

Original activity = 0.05629 µCi = 16,880 α/min on 3/01/2005

Certified Emission rate = 16,880 α/min (2π) OR **33,760 α/min (4π) on 2/17/2005 (^{239}Pu)**

DATE	*ACTIVITY (µCi)*	*ACTIVITY (dpm 4π)*	*ACCEPTANCE RANGE Dpm 4π*
Jan. 1, 2013	0.05628	33,752	27,002 – 40,502
Jan. 1, 2014	0.05628	33,751	27,001 – 40,501
Jan. 1, 2015	0.05627	33,750	27,000 – 40,501

Mark Sells, January 2, 2013

Appendix 17.3 cont'd, Example Calibration Source Information Sheet, reverse

2013 CERMER CALIBRATION SOURCE INFORMATION SHEET

Gamma Source RS-94040, ^{137}Cs

Original activity = 5.0 µCi on August 1994

DATE	ACTIVITY (µCi)	ACTIVITY (dpm 4π)	ACCEPTANCE RANGE Dpm 4π
Jan. 1, 2013	3.3	N/A	N/A
Jan. 1, 2014	3.2	N/A	N/A
Jan. 1, 2015	3.1	N/A	N/A

Micro-R meter 2012 data, n=65, avg. response = 800 µR/hr. (acceptable resp. = 640 – 960 uR/hr.)

Gamma Source RS-8049, ^{137}Cs

Original activity = 1.0 µCi on Jan 2009

DATE	ACTIVITY (µCi)	ACTIVITY (dpm 4π)	ACCEPTANCE RANGE Dpm 4π
Jan. 1, 2013	0.91	N/A	N/A
Jan. 1, 2014	0.89	N/A	N/A
Jan. 1, 2015	0.87	N/A	N/A

Micro-R meter 2012 data, n=65, avg. response = 240 µR/hr. (acceptable resp. = 192 – 288 uR/hr.)

Alpha Source C4-070, ^{230}Th

Original activity = 0.06006 µCi on March 1, 2005

Certified emission rate = 67,330 α/min (2π) OR **134,660 α/min (4π) on 2/23/2005 (^{239}Pu)**

DATE	ACTIVITY (µCi)	ACTIVITY (dpm 4π)	ACCEPTANCE RANGE Dpm 4π
Jan. 1, 2013	0.06006	134,650	107,720 – 161,580
Jan. 1, 2014	0.06006	134,649	107,719 – 161,579
Jan. 1, 2015	0.06006	134,648	107,718 – 161,578

Mark Sells, January 2, 2013

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
NATIONAL CENTER FOR RADIATION FIELD OPERATIONS
4220 SOUTH MARYLAND PARKWAY, BLDG C
LAS VEGAS, NV 89119-7533

OFFICE OF
AIR AND RADIATION

May 27, 2014

MEMORANDUM

SUBJECT: SOP Reassignments

FROM: Jeremy Johnson, Director
Center for Radiation Preparedness and Response
Office of Radiation and Indoor Air

Ed Wilds, Director
Center for Planning and Training
Office of Radiation and Indoor Air

TO: QA File

The purpose of this memo is to update the QA file regarding the responsible official (RO) and technical reviewer assignments for active and draft CRPR standard operating procedures (SOPs). The responsible official and/or technical reviewer for multiple SOPs have been reassigned. Below, each SOP is listed by number and title with their responsible official and the technical reviewer. Changes made from previous assignments are noted by an asterisk ("*"). Further assignments or changes in assignment will be made by memo to the CRPR QA file that is maintained by the CRPR quality assurance coordinator.

RPR-205, **Operation of Air Samplers Without Flow Measurement Capability**
Responsible Official: Gary Spradlin
Technical Reviewer: Michael Messer*

RPR-206, **DL-28B Low Volume Air Sampler**
Responsible Official: Gary Spradlin
Technical Reviewer: Michael Messer*

RPR-207, **DH-504 High Volume Air Sampler**
Responsible Official: Gary Spradlin
Technical Reviewer: Michael Messer*

RPR-220, **Environmental Sampling Procedures**
Responsible Official: Mark Sells
Technical Reviewer: Michael Messer*

RPR-271, **Wipe Procedure for Removal Contamination**
Responsible Official: Sandra Elkouz*
Technical Reviewer: Mark Sells

RPR-301, **Operation of High Pressure Ion Chamber**
Responsible Official: Gary Spradlin
Technical Reviewer: Scott Faller

RPR-303, **Operation of the Sodium Iodide Ruggedized/Submersible Detector**
Responsible Official: Scott Faller
Technical Reviewer: Malek Chatila*

RPR-314, **Collection of In-Situ HPGe Gamma-Ray Spectra for Field Measurements**
Responsible Official: Scott Faller
Technical Reviewer: Malek Chatila*

RPR-330, **Survey Techniques for Contamination and Exposure Rate Monitoring**
Responsible Official: Malek Chatila*
Technical Reviewer: Mark Sells

RPR-331, **Assembly and Functional Testing of Ludlum Model 239-1F Floor Monitor"**
Responsible Official: Christine-May Matthews*
Technical Reviewer: Mark Sells

RPR-340, **Field Instrument QC and Operating Guides**
Responsible Official: Mark Sells
Technical Reviewer: Malek Chatila*

RPR-354, **Operation of the Ludlum Model 2929 Dual Channel Scaler**
Responsible Official: Malek Chatila*
Technical Reviewer: Greg Budd*

RPR-361, **Personal Digital Assistant Operation with the RadNet Deployable System**
Responsible Official: Mike Messer
Technical Reviewer: Natalia Brooks*

RPR-364, **Environmental Radiation Scanner Van Operation**
Responsible Official: Scott Faller
Technical Reviewer: Greg Budd*

RPR-405, **Air Sampler Maintenance**

Responsible Official:	Gary Spradlin
Technical Reviewer:	Michael Messer*

RPR-410, **Calibration of F&J Venturi Flow Measurement Devices, and Samplers**

Responsible Official:	Gary Spradlin
Technical Reviewer:	Mike Messer*

RPR-440, **Radiation Detection Instrumentation QA Checks**

Responsible Official:	Malek Chatila*
Technical Reviewer:	Greg Budd*

RPR-803, **Sampling Equipment Decontamination**

Responsible Official:	Scott Faller*
Technical Reviewer:	Greg Budd*

RPR-808, **Contamination Control Operations**

Responsible Official:	Mark Sells
Technical Reviewer:	Natalia Brooks*

RPR-810, **Sample Control**

Responsible Official:	Mark Sells
Technical Reviewer:	Sandra Elkouz

RPR-850, **Personnel Monitoring for Contamination**

Responsible Official:	Natalia Brooks*
Technical Reviewer:	Christine-May Matthews*

RPR-851, **Emergency Response Personnel Decontamination Procedure**

Responsible Official:	Natalia Brooks*
Technical Reviewer:	Christine-May Matthews*

RPR-501, **Cleaning Laboratory Supplies/Glassware**

Responsible Official:	Christine-May Matthews
Technical Reviewer:	Sandra Elkouz

RPR-601, **Gamma Spectrometry in the MERL**

Responsible Official:	Mark Sells*
Technical Reviewer:	Scott Faller

RPR-604, **Proportional Counting in the MERL**
Responsible Official: Christine-May Matthews
Technical Reviewer: Gregg Dempsey

RPR-608, **Liquid Scintillation Counting in the MERL**
Responsible Official: Sandra Elkouz
Technical Reviewer: Gregg Dempsey*

RPR-611, **Quality Control Checks of Automatic Pipettes**
Responsible Official: Christine-May Matthews
Technical Reviewer: Sandra Elkouz

RPR-612, **Quality Control Checks of Balances**
Responsible Official: Christine-May Matthews
Technical Reviewer: Sandra Elkouz

RPR-650, **Sample Receipt and Preparation in the SPL**
Responsible Official: Sandra Elkouz
Technical Reviewer: Christine-May Matthews

cc: NCRFO Management
NCRFO Staff

National Center for Radiation Field Operations	Number RPR-851	Page Page 1 of 22
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Emergency Response Personnel Decontamination Procedure

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SOP REVISIONS

Rev. No.	Rev. Date	Revision	Responsible Official
00	Apr. 13, 2012	Initial Issue	L. Kelly
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1.0 PURPOSE

During emergency response or site cleanup activities, personnel could potentially become contaminated with radioactive material. Contamination can be transferred to clothing, tools, equipment, objects, vehicles, and/or body parts coming in contact with the radioactive material. To minimize the spread of radiological contamination beyond the established controlled areas, contamination control corridor, hotlines, or designated decontamination areas must be setup to survey field team members exiting from controlled areas to determine the presence and location of contamination (see SOP RPR-808, *Contamination Control Operations*). The purpose of this procedure is to describe appropriate methods for decontaminating personnel who have become contaminated with radioactive material during a response.

2.0 SCOPE AND APPLICABILITY

2.1 Scope, Application, Method Summary

2.1.1 Before decontamination can occur, full external surveys of personnel shall be performed to determine all locations of contamination. Surveying helps identify contamination to prevent further spread of contamination onto other objects and/or personnel. The procedure for personnel surveys is not in the scope of this procedure. For instructions on proper surveying techniques, please refer to the SOP RPR-850 *Personnel Monitoring for Contamination.*

2.1.2 Decontamination procedures can vary depending on the type of radionuclides present and the chemical form of the contaminant. This procedure only describes common decontamination procedures used for removing contaminants from external surfaces of the body. For more advanced decontamination procedures, please contact the Radiation Safety Officer (RSO) and/or site Health and Safety Officer (HSO) for further guidance.

2.1.3 During decontamination procedures, radioactive waste will be produced. It is important to plan the potential amount, storage, and removal of waste before decontamination procedures begin. All decisions shall be reviewed and accepted by the RSO and/or site HSO before decontamination can occur. This procedure for personnel decontamination does not address the amount of waste produced, storage of waste, treatment, volume reduction, and/or waste removal.

2.2 Interferences

Constant surveying of the decontamination area is essential. If contamination of the decontamination area is found, decontamination operations must be stopped to prevent the spread of contamination and/or cross contamination. The decontamination area must be cleaned before proceeding with personnel decontamination.

2.3 Potential Problems

Personnel who are working in contaminated areas may become internally contaminated. External contamination may enter the body via absorption, inhalation, injection, and/or ingestion. If internal contamination is suspected, immediately contact the RSO for additional monitoring and dose analysis. This procedure does not address internal contamination.

3.0 DEFINITIONS

3.1 ALARA — As low as reasonably achievable. The aim is to minimize the risk of radioactive exposure while keeping in mind that some exposure is acceptable and necessary, in order to accomplish the given task, or mission.

3.2 Acceptance Criteria — refer to the site specific requirement for free release. For sites that do not specify an acceptance criterion, the RSO or site HSO will specify their own release limit. However, the free release value cannot exceed the values as specified in 10 CFR 20 and summarized in Appendix 17.2.

3.3 Contamination — The deposition of radioactive material in any place where it is not desired.

3.4 Cross Contamination — contamination of the PPE or personnel caused by the introduction of a contaminant from another location.

3.5 CRC or CCC — Contamination Reduction Corridor or Contamination Control Corridor.

3.6 Decontamination — The process of removing radioactive contamination from clothing, tools, equipment, objects, vehicles, and/or body.

3.7 Hotline — An area where samples are received and processed; personnel, equipment, and vehicles are surveyed; and decontamination operations can be performed. The Hotline can also be referred to as the 'Contamination Reduction Corridor' or 'Contamination Control Corridor'.

3.8 PPE — Personal Protective Equipment, including but not limited to respiratory protection devices, protective clothing, gloves, boots, and boot covers, etc.

3.9 RSO — refers to the site or NCRFO's Radiation Safety Officer.

3.10 Radiation Surveyor — describes personnel located within or near the hotline whose duties include surveying personnel and/or equipment for contamination, locating contamination, and resurveying to determine the success of decontamination efforts.

3.11 SHEM — refers to NCRFO's Safety and Health Environmental Manager (can also be referred to as the site Health and Safety Officer).

3.12 SOP — Standard Operating Procedure.

3.13 Team Leader — individual who will take responsibility for the health and safety of their team as well as completion of all documentation generated. If decontamination occurs in the field (e.g. between sampling), the Team Leader is the same person as the Field Team Leads. If decontamination occurs in a hotline, the Team Leader will be the Decontamination Specialist.

4.0 PERSONNEL

4.1 PERSONNEL QUALIFICATIONS

4.1.1 Personnel who perform the tasks described in this SOP must be provided with training, followed by demonstration of proficiency. If training courses are not available, personnel will learn to perform this procedure under the direct supervision of a Subject Matter Expert (SME). Training and demonstrations of proficiency must be performed and documented in accordance with the Center for Radiation Preparedness and Response (CRPR) Quality Assurance Manual and must be consistent with the National Center for Radiation Field Operations (NCRFO) Quality Management Plan (QMP, also R&IENL QMP).

4.1.2 Personnel who perform the tasks described in this SOP must have received radiation safety training within a 12-month period as specified in the Radiation Safety Manual, with training records on file with the RSO.

4.1.3 Personnel who perform the tasks described in this SOP must have the minimum training listed below or the equivalent associated refresher course within the previous 12 months, and the applicable documents to indicate their status:

- EPA Medical Monitoring
- HAZWOPER 40-Hr. Certification or an 8-Hr. HAZWOPER Refresher Course (as appropriate)
- Radiation Safety Training

In addition, First Aid/CPR certification w/ AED essential training via the American Red Cross or the American Heart Association must have been received within the previous 24 months.

4.1.4 Specific requirements are needed for personnel staffing decontamination areas within a hotline. See SOP RPR-808 *Contamination Control Operations* for further qualifications.

4.1.5 The Team Leader is responsible for all decision making during the decontamination process including pre-planning and completion of documentation. See definition for "Team Leader."

4.2 PERSONNEL RESPONSIBILITIES

4.2.1 Personnel who perform the tasks described in this SOP must be aware of and comply with site specific requirements put forth in the site Health and Safety Plan (HASP) for the

project or incident, and must follow ALARA principles, awareness of exposure and dose limits and turnback levels determined for the project.

4.2.2 Personnel who perform the tasks described in this SOP must wear and manage a personal dosimeter to track received dose. The dosimeter may be a passive thermo-luminescent dosimeter (TLD) or an electronic personal dosimeter (EPD).

4.2.2 All personnel who perform the tasks described in this SOP are responsible for following the procedures and quality assurance requirements described within this SOP and the CRPR QAM. All personnel must be aware of and comply with site specific regulations and QA protocols as defined by organizational management and/or the project Quality Assurance Project Plan (QAPP) or other environmental sampling plan.

4.2.3 Personnel who are involved in emergency response or other applications of radiation monitoring are responsible for assuring that instrumentation is maintained in a useable condition as outlined in the CRPR QAM.

4.2.4 Repairs of adjustments of settings, which could affect how the instrument responds to radiation detection and measurements, are performed by the Field Radiation Instrument Manager (Instrument Manager). In accordance with the CRPR QAM, it is the responsibility of the user to notify the Instrument Manager, Radiological Emergency Response Team (RERT) Commander, Team Leader, or other appropriate management when an instrument is out of calibration, performance degrades, or damage has occurred.

4.2.5 Any personnel entering a potentially contaminated area must take precautions to avoid becoming contaminated with radioactive materials. Examples of contamination control may include placing plastic onto the ground when kneeling or setting instruments down, wrapping instruments with plastic when possible, removing/reapplying gloves if contaminated.

4.2.6 Personnel performing decontamination must survey the area along with their PPE to ensure that no cross contamination has occurred. If contamination is found, the area must be decontaminated before decontamination of field team personnel. In addition contaminated PPE must be replaced with clean PPE before decontamination can occur.

5.0 EQUIPMENT AND SUPPLIES

If practical, the following items shall be stored or be readily accessible.

- Mild liquid soap
- Mild bar soap
- Abrasive soap
- Shampoo
- Plastic gloves
- Plastic booties
- Scissors

- Cotton-tipped swabs
- Smears or Swipes
- Soft towels
- Masslinn cloth
- Soft bristle brushes
- Ear plugs
- Duct and masking tape
- Cotton sheeting/soft towels
- Absorbent cotton pads
- Granulated laundry soap and corn meal (50-50 mix)
- Operational decontamination shower or approved substitute
- Hand cream or Lanolin moisturizing lotion
- RADIAC WASH or equivalent
- Rad-Con Foam or equivalent
- Radiation Survey Instruments (appropriate for anticipated radiation types/energies)
- Portable Contamination Survey Instruments (appropriate for anticipated radiation types/energies)

6.0 REAGENTS AND STANDARDS

Currently, no reagents or standards are used for decontamination besides the reagents listed above. DO NOT mix reagents or experiment with new reagents during decontamination procedures.

7.0 HEALTH AND SAFETY

7.1 Health Cautions

7.1.1 Field projects encompass a wide range of hazards. Take precautions while performing personnel decontamination including the buddy system, line of site operations, and maintaining communication with others. The site HASP shall be reviewed and followed.

7.1.2 In the event that an injured person needs to receive lifesaving medical assistance, the person should be passed immediately through the hotline for transport to a medical facility. Priority must be given to lifesaving actions over decontamination. Wrap the affected person in cotton sheeting to contain any external contamination as much as possible. Transport and hospital personnel will need to be aware of any potential contamination located on the victim to minimize contaminating transport vehicles and support facilities.

7.1.3 Eating and drinking within the hotline is prohibited. Personnel working in the decontamination area must be given the opportunity to take breaks in a clean area where food and water are available.

7.1.4 Report all injuries, accidents or near-misses to the Team Leader, and the SHEM or site HSO.

7.2 Equipment Cautions

Always be aware of electrical supplies, cords, devices, or other electrical equipment and use appropriate care when handling electrical devices especially near water. Electrical equipment should be connected through a Ground Fault Interrupter (GFI) equipped outlet.

8.0 SAMPLE COLLECTION, PRESERVATION, AND STORAGE

N/A

9.0 CALIBRATION AND STANDARDIZATION

All survey instruments shall meet RERT calibration requirements, including conformance to ANSI N323 or more stringent requirements, for use in an emergency response situation. These requirements include but are not limited to:

- Batteries must be tested
- Calibration documents must be available for all instruments.
- All survey instrument shall have been calibrated during the previous 12 months
- The instrument must meet routine daily quality control criteria.

Calibration and source check records shall be retained as required in the CRPR QAM.

10.0 PROCEDURE

10.1 Initial Surveys and Observations

10.1.1 Examine the individual for signs warranting medical attention. If life-threatening issues or injuries are observed, medical assistance must take priority over decontamination. Quick and simple methods to minimize the spread of contamination can be performed as long as decontamination does not delay medical treatment. Examples may include covering the areas of contamination in soft towels and/or covering the surfaces, where the individual is placed, with plastic. The emergency medical team must be notified of any known or potential areas of contamination on the individual. Contamination will be documented on the RPR-850 *Personnel and Clothing Contamination Report,* Appendix 17.1. A copy should be given to the assigned medical team.

10.1.2 If no signs of medical attention are observed, decontamination can be performed using the general process as described in the next section.

10.2 Prior to Decontamination

10.2.1 A whole body survey of the individual must be performed before entering a non-contaminated area/clean zone from a contaminated area/hot zone. Refer to RPR-850 *Personnel Monitoring for Contamination* for personnel survey techniques.

10.2.2 Individuals must be scanned by an appropriate radiation detector (such as a portal monitor and/or hand-held radiation instrument) sensitive enough to detect the radionuclide of interest. If contamination is found on the individual by the portal monitor, a radiation surveyor must perform a whole body survey on the individual to locate contamination.

10.2.3 Techniques and procedures for surveying personnel contaminated with radioactive material are detailed in SOP RPR-850.

10.2.4 If contamination is not detected, the individual must continue through the decontamination line, known as a "Hotline", and follow the doffing instructions given by the hotline personnel. Procedures for the hotline can be found in the SOP RPR-808 *Contamination Control Operations*.

10.2.5 If contamination is detected, the individual must follow instructions of the hotline personnel to the designated gross decontamination area within the hotline. Hotline personnel will document contamination on the RPR-850 *Personnel and Clothing Contamination Report,* Appendix 17.1 which will be sent in a plastic bag with the person requiring decontamination to the decontamination area.

10.2.6 Depending on the type, extent, and location of contamination, the decontamination techniques will vary. The following sections are decontamination techniques to be used based on specific contamination situations.

10.3 Minor Clothing Contamination

10.3.1 The first attempt to remove contamination from clothing should be performed using the adhesive side of duct or masking tape. Place the piece of tape, sticky side towards the contaminated area, and lift. Survey the affected area to determine effectiveness of decontamination attempt(s). Record survey results on the RPR-850 *Personnel and Clothing Contamination Report,* Appendix 17.1. Contaminants should adhere to the sticky side of the tape. Survey the tape and place into radioactive trash if contaminated. If the acceptance criteria determined in this SOP's *Surface Contamination Values*, Appendix 17.1 or the site QAPP is not reached after three attempts go to step 10.3.2 and 10.3.3.

10.3.2 If the radionuclide has a short half-life, the clothing can be confiscated and held in a plastic bag until the radionuclide has decayed for at least 10 half-lives. Attach the RPR-850 *Personnel and Clothing Contamination Report,* Appendix 17.1 to the bag. The clothing must be resurveyed to determine if it can be released back to the individual. Record survey results on the RPR-850 *Personnel and Clothing Contamination Report,* Appendix 17.1 attached to the bag.

10.3.3 If the tape method was not effective, the clothing should be confiscated and placed in a plastic bag with a copy of the RPR-850 *Personnel and Clothing Contamination Report,* Appendix 17.1 attached to the bag and surrendered to the Team Leader.

Washing of clothing should not be performed due to the amount of liquid waste generated.

10.4 Skin Contamination

When performing decontamination using water or soap/chemical solutions, always collect and segregate waste water and any other decontamination waste for proper handling. Manage all waste products as required in project planning documents (see section 15).

10.4.1 The first attempt to remove contamination from skin should be performed using the adhesive side of duct or masking tape. Place the piece of tape, sticky side towards the contaminated area, and lift. Survey the affected area to determine effectiveness of decontamination attempt(s). Record survey results on the RPR-850 *Personnel and Clothing Contamination Report,* Appendix 17.1. Contaminants should adhere to the sticky side of the tape. Survey the tape and place into radioactive trash if contaminated. If the acceptance criteria determined in this SOP's *Surface Contamination Values*, Appendix 17.1 or the site QAPP is not reached after three attempts go to step 10.4.2.

10.4.2 If adhesive tape is not a viable option (contaminated area is wet, body hair, etc.), apply mild soap such as RADIAC WASH or RAD-CON FOAM with a dampened cloth (tepid water between 20°C and 30°C) and gently rub the affected area with a circular motion, flush the affected area thoroughly with tepid water and pat the area dry with a clean towel. Survey the area after each attempt. Record survey results on the RPR-850 *Personnel and Clothing Contamination Report,* Appendix 17.1. If the acceptance criteria determined in this SOP's *Surface Contamination Values*, Appendix 17.1 or the site QAPP is not reached after three attempts go to step 10.4.3.

NOTE: Prior to skin decontamination; consult the affected individual regarding any known allergies to soap products. If skin irritation is noticed or the contaminated individual experiences discomfort at any time during the skin decontamination process, decontamination efforts should be suspended. Consult with the SHEM or site HSO and, if determined necessary, wrap the affected area in soft towels or equivalent to control the spread of contamination and transport to the nearest emergency room/hospital with decontamination facilities. When performing skin decontamination, extreme care should be taken to avoid breaking the skin.

10.4.3 Mix granulated laundry soap and corn meal into a 50-50 mixture. Add water to create a thick paste. Scrub the affected area with the paste using a mild scrubbing action. Use care not to irritate the skin. Rinse the area with water and pat dry. Survey the area after each attempt. Record survey results on the RPR-850 *Personnel and Clothing Contamination Report,* Appendix 17.1. If the acceptance criteria determined in this SOP's *Surface Contamination Values*, Appendix 17.1 or the site QAPP is not reached after three attempts proceed to step 10.4.4 if the contaminated body part is a hand or foot, otherwise proceed to section 10.4.5.

10.4.4 Sweating is another method for removing contamination on hands and feet. Place the bare hand or foot into a plastic glove or bootie (as applicable) and seal with tape. Let the hand or foot sweat for up to 2 hours or until the hand or foot is sweating profusely. Remove the glove or bootie and flush the hand or foot immediately with tepid water. Survey the area after each attempt. Record survey results on the RPR-850 *Personnel and Clothing Contamination Report,* Appendix 17.1. If the acceptance criteria determined in this SOP's *Surface Contamination Values*, Appendix 17.1 or the site QAPP is not reached after three attempts proceed to step 10.4.5.

10.4.5 Abrasive skin decontamination techniques should be avoided if possible and used only as a last resort. If abrasive skin decontamination technique is needed, decontamination shall be performed under the supervision of qualified medical personnel. Use a mildly abrasive hand soap and soft bristle brush. Apply light pressure with a heavy lather. Wash for two minutes and then flush thoroughly. Use care not to irritate the skin. Survey the area after each attempt. Record survey results on the RPR-850 *Personnel and Clothing Contamination Report,* Appendix 17.1. If the acceptance criteria determined in this SOP's *Surface Contamination Values*, Appendix 17.1 or the site QAPP is not reached after three attempts consult with the SHEM or the site HSO for transport to the nearest emergency room/hospital that has decontamination facilities.

NOTE: If skin irritation is noticed or the contaminated individual experiences discomfort at any time during the skin decontamination process, field decontamination efforts should be suspended. Consult with the SHEM or the site HSO and, if determined necessary, wrap the affected area in soft towels or equivalent to control contamination and transport to the nearest emergency room/hospital that has decontamination facilities.

10.4.6 If any of these decontamination techniques are successful, apply hand cream or lanolin to prevent chapping after decontamination is completed.

10.5 Hair Contamination

When performing decontamination using water or soap/chemical solutions, always collect and segregate waste water and any other decontamination waste for proper handling. Manage all waste products as required in project planning documents (see section 15).

10.5.1 Seal the contaminated individual's ears with ear plugs. Exercise care to prevent spread of contamination to the ear canal.

10.5.2 Place a clean towel over the individual's face and around the neck.

WARNING: Instruct the individual to keep the mouth and eyes shut during decontamination.

10.5.3 Lean the contaminated individual over a sink or other collection basin/tub (or enter a decontamination shower) and dampen the hair. *Do not* soak the hair.

10.5.4 Apply shampoo and work up a good lather. Only use shampoo that does not include conditioner. Rinse with just enough water to remove shampoo from hair.

10.5.5 Completely dry the hair with a clean towel. DO NOT use a blow dryer.

10.5.6 Resurvey the hair. DO NOT resurvey damp or wet hair.

10.5.7 Document results on RPR-850 *Personnel and Clothing Contamination Report,* Appendix 17.1.

10.5.8 If the acceptance criteria as determined in this SOP's *Surface Contamination Values*, Appendix 17.1 or the site QAPP is not met, repeat steps 10.5.2 through 10.5.7 a maximum of two more times.

10.5.9 If acceptance criteria still cannot be met, consult with the SHEM or the site HSO for transport to the nearest emergency room/hospital that has decontamination facilities.

10.6 Mouth, Nasal, Eye, and Ear Canal Contamination

When performing decontamination using water or soap/chemical solutions, always collect and segregate waste water and any other decontamination waste for proper handling. Manage all waste products as required in project planning documents (see section 15).

10.6.1 *Mouth contamination*:

- Use moistened cotton-swabs to survey the mouth for contamination. Carefully swab the affected area. Count swabs on the appropriate counting instrument to determine the activity.
- Document results on RPR-850 *Personnel and Clothing Contamination Report,* Appendix 17.1.

NOTE: Advise the affected individual not to swallow the rinse water.

- If decontamination is necessary, flush the mouth with large amounts of tepid water. Swab the mouth again and count the swab. If the acceptance criteria as determined in this SOP's *Surface Contamination Values*, Appendix 17.1 or the site QAPP is not met, flush the mouth, swab and count the swab up to two more times.
- If acceptance criteria still cannot be met, consult with the SHEM or the site HSO for transport to the nearest emergency room/hospital that has decontamination facilities.

10.6.2 *Nasal contamination*:

- Direct the contaminated individual to gently blow his/her nose into a Kleenex or equivalent expelling as much mucus as possible.
- Perform a survey of the Kleenex and its contents.
- Document results on RPR-850 *Personnel and Clothing Contamination Report,* Appendix 17.1.
- If the acceptance criteria as determined in this SOP's *Surface Contamination Values*, Appendix 17.1 or the site QAPP is not met, repeat the first three steps in 10.6.2 up to two more times. If contamination remains, continue to the following steps.
- Have the contaminated individual bend his/her head down. Gently flush the affected area with tepid water. *Do not* force water up the nose. Caution the contaminated individual not to swallow or breathe in the rinse water. Follow the first three steps in 10.6.2 up to two more times. If acceptance criteria still cannot be met, consult with the SHEM or the site HSO for transport to the nearest emergency room/hospital that has decontamination facilities.

10.6.3 *Eye and ear canal contamination*:

NOTE: Only qualified medical personnel shall perform decontamination of the eyes and/or ear canals. The radiation surveyor or designee will support medical personnel during decontamination efforts.

- Have qualified medical personnel flush or irrigate the affected area(s) with large amounts of tepid water.
- Survey the eyes and/or ear canal after flushing is completed.
- Record results on RPR-850 *Personnel and Clothing Contamination Report,* Appendix 17.1.
- If the acceptance criteria as determined in this SOP's *Surface Contamination Values*, Appendix 17.1 or the site QAPP is not met, attempt this method up to two more times.
- If acceptance criteria still cannot be met, consult with the SHEM or the site HSO for transport to the nearest emergency room/hospital that has decontamination facilities.

10.7 Gross Skin Contamination

10.7.1 Adjust the decontamination shower temperature to lukewarm temperature and moderate flow. Have the contaminated individual enter the shower.

NOTE: If a decontamination shower is not readily available, the radiation surveyor or designee may substitute alternate sources of wash water (water hose, water in buckets, etc.) at the designated decontamination location. If an alternate is used, the radiation surveyor or designee shall be responsible for the collection of waste water.

10.7.2 Instruct the individual to work soap into a lather washing the affected area(s) thoroughly.

NOTE: Advise the individual to keeping the lather below the shoulders and carefully using the soap, hands, or washcloth. The individual should work from top to bottom to avoid contaminating other body parts.

10.7.3 Instruct the individual to rinse thoroughly and pat the body dry with a towel.

10.7.4 The radiation surveyor or designee shall perform a whole body contamination survey.

10.7.5 Document results on the RPR-850 *Personnel and Clothing Contamination Report,* Appendix 17.1.

10.7.6 If the acceptance criteria as determined in this SOP's *Surface Contamination Values*, Appendix 17.1 or the site QAPP is not met, attempt this method up to two more times.

10.7.7 If acceptance criteria still cannot be met, consult with the SHEM or the site HSO for transport to the nearest emergency room/hospital that has decontamination facilities.

10.8 Hot Particle Contamination

Hot particles are microscopic pieces of radioactive material that may become lodged onto a person's skin, clothing, or equipment. Hot particles are not visible to the naked eye. Because hot particles have high activities of radiation, the particles tend to deliver a concentrated dose of radiation to a small area of skin. It is vital to remove hot particles as soon as possible to reduce the dose of radiation to a person's skin.

10.8.1 Attempt to remove the hot particle contamination by gently pressing a piece of tape to the skin or clothing and lifting the particle off.

10.8.2 Survey the piece of tape to determine if the particle is removed from the affected area.

10.8.3 Survey the affected area (skin or clothing) to ensure that all activity has been removed.

10.8.4 Document results on the RPR-850 *Personnel and Clothing Contamination Report,* Appendix 17.1.

10.8.5 If the hot particle is on the skin, apply skin decontamination procedures found in Section 10.4 to remove the hot particle(s) from the skin. Place tape containing the hot particle in a plastic bag with an attached copy of RPR-850 *Personnel and Clothing Contamination Report,* Appendix 17.1. Proceed to step 10.8.7.

10.8.6 If the hot particle is on clothing and cannot be removed, secure the hot particle in place by taping over and under the area where the hot particle is located on the clothing. Tape must be placed on both sides of clothing. Confiscate the clothing item by placing in a plastic bag with an attached copy of RPR-850 *Personnel and Clothing Contamination Report,* Appendix 17.1. Proceed to step 10.8.7.

10.8.7 Retain the hot particle as radioactive waste. Depending on the activity of the hot particle, the hot particle may need to be segregated into a shielded container. Consult with the RSO and/or a Health Physicist to determine shielding requirements.

10.9 Post-Decontamination and Documentation

10.9.1 Decontamination shall be determined to be complete when the decontamination levels do not exceed the limits listed in this SOP's *Surface Contamination Values*, Appendix 17.1 or the site QAPP. Decontamination can be stopped when the radiation surveyor or designee can no longer detect contamination above the limits using portable frisking instrumentation on an individual or the individual has successfully exited a portal monitor without an alarm.

10.10.2 All decontamination activities shall be documented on the RPR-850 *Personnel and Clothing Contamination Report,* Appendix 17.1. The RSO or designee may recommend that any individual who has undergone decontamination be subject to bio-assay or a whole body count. Dose estimates from skin exposures (due to hot particle contamination) shall be calculated per the RSO's direction.

11.0 QUALITY ASSURANCE

11.1 Quality Control

11.1.1 Maintain a clean work environment and use appropriate survey and decontamination procedures to avoid the spread of contamination.

11.1.2 Take precautions to prevent contamination of documents or records that are generated during hotline/decontamination operations.

11.1.3 Instrument QC checks, including background checks, must be performed as specified in the relevant QAPP. At a minimum, QC checks must be performed at the beginning and end of use/shift for each location. Place the probe firmly against the check source using the same geometry (position) each time, and note the measurement in either a Daily Instrument QC Check Form, such as the FRMAC *Daily Instrument QC Check Form* (see RPR-850, Appendix 17.2), the instrument logbook, or both. Verify that the measurement is within $\pm$20% of the expected response and note that acceptance.

11.1.4 The surveyor shall maintain all instruments in a clean and uncontaminated condition during use. In the event the instrument or detector should become contaminated, it shall be reported and returned to the Instrument Manager for

assessment and decontamination. The Instrument Manager will work with the Decontamination Specialist to decontaminate the instrument.

11.2 Records Management

11.2.1 All records pertaining to environmentally related measurements and all documents relating to the Quality System must be archived, retained, and disposed of according to the requirements in the NCRFO QMP and the CRPR QAM.

11.2.2 Documentation that field team members generate in the field must be maintained by the Team Leader. This may include but is not limited to copies of forms, RPR-850 *Personnel and Clothing Contamination Report,* Appendix 17.1 and FRMAC *Daily Instrument QC Check Form* located in RPR-850, Appendix 17.2.

11.3 Computer Hardware and Software Management

N/A-Currently, no computer hardware is used for personnel decontamination.

11.4 Procurement Requirements

All procurements are made following the requirements in the Federal and EPA acquisition regulations as stated in NCRFO's QMP. The use of purchase cards for procurement must follow the NCRFO Purchase Card Policy.

11.5 Assessments

11.5.1 This SOP shall be reviewed at least once annually to assure that the procedures are appropriate and comprehensive.

11.5.2 The effectiveness of this procedure shall be evaluated at least annually by those personnel immediately responsible for overseeing and/or performing the tasks described by the procedure. Results of any review shall be used to improve the process and to revise this SOP and related quality documentation. Results shall also be documented per SOP RIE-101.

11.5.3 This document must reflect the quality requirements for all organizational parts of NCRFO. If changes to the organizational structure of NCRFO occur, this document must be reviewed and revised to reflect those changes.

11.6 Corrective Actions

If a procedural non-conformance is discovered or one occurs due to unforeseen circumstances, the non-conformance issue must be documented and corrective action process followed as defined in the CRPR QAM and NCRFO QMP.

12.0 DATA ANALYSIS AND CALCULATION

For contamination levels, the surveyor must be able to convert dpm/100cm^2 (the units of the limits located in this SOP's *Surface Contamination Values*, Appendix 17.1) to cpm (the units of the values produced by the instrument) to know when the readings displayed on the detector, in units of cpm, exceed the allowable contamination limits, in dpm/100cm^2, located in Appendix 17.1 of this procedure. Converting dpm/100cm^2 to cpm:

$$\frac{dpm}{100cm^2} \times \mathrm{A} \times \varepsilon = \mathrm{cpm}$$

Where A is the active area of the detector face in units of cm^2
ε is the efficiency of the detector for a specific type of radionuclide

13.0 DATA REVIEW

Data obtained during the performance of this SOP must be reviewed as required by NCRFO data review policy found in NCRFO's QMP and the CRPR QAM.

14.0 METHOD PERFORMANCE

N/A

15.0 ENVIRONMENTAL MANAGEMENT SYSTEM

15.1 Pollution Prevention

15.1.1 It is expected that contaminated materials in the form of PPE, plastic bags, tape, brushes, towels, plastic sheeting, will be left for disposal at the site CCC. It is important to segregate and contain contaminated materials to prevent the spread of contamination into the environment.

15.1.2 If contaminated water is part of the waste stream for decontamination activities, careful planning must be made to assure that all contaminated water is contained within the decontamination area in appropriate storage containers, or evaporation ponds as specified in the site QAPP.

15.1.3 In some cases the wastewater generated during operations could potentially be re-directed back to previously contaminated areas for later cleanup, or into local waste streams for treatment. These options should only be considered as a last resort and must have the approval of all stakeholders (local governments and public).

15.2 Waste Management

15.2.1 Segregate all contaminated and non-contaminated waste materials. Do NOT place contaminated waste into containers that are identified and marked for non-contaminated

waste. The non-contaminated waste can be disposed of using normal waste stream methods.

15.2.2 Clearly identify all receptacles for waste materials. All radioactive and non radioactive waste containers must be segregated. Different color waste containers, signs on containers, or other obvious markings can be used to distinguish radioactive waste from non radioactive waste. Use Radioactive Waste labels only when appropriate.

15.2.3 All contaminated materials (tools, tyvek suits, etc.) collected during decontamination operations must be placed into containers that are clearly marked and identified as contaminated. These items must be disposed of following regulatory requirements for the type of waste being generated (low level radioactive, mixed waste or hazardous waste, etc.). Contain and segregate these materials and coordinate their removal and proper disposal with the project RSO.

16.0 REFERENCES

16.1 Specifications and Requirements

16.1.1 American National Standards Institute, *American National Standard Radiation Protection Instrumentation Test and Calibration, Portable Survey Instruments,* ANSI N323A-1997.

16.1.2 Radiation and Indoor Environments National Laboratory, *Standard Operating Procedure Development,* RIE-101 R6, August, 2012.

16.1.3 Radiation and Indoor Environments National Laboratory, *Quality Management Plan*, Revision 4, May, 2012 (also NCRFO QMP).

16.1.4 Radiation and Indoor Environments National Laboratory, *R&IE Purchase Card Internal Standard Operating Policy and Procedures*, May, 2011 (also NCRFO Purchase Card Policy).

16.1.5 Radiation and Indoor Environments National Laboratory, *Radiation Safety Manual*, November, 2012 (also NCRFO RSM).

16.1.6 Center for Radiation Preparedness and Response, *Quality Assurance Manual*, August 2013.

16.1.7 Center for Radiation Preparedness and Response, SOP RPR-330, *Survey Techniques for Contamination and Exposure Rate Monitoring*, August 2013

16.1.8 Center for Radiation Preparedness and Response, SOP RPR-808, *Contamination Control Operations*, August 2013

16.1.9 Center for Radiation Preparedness and Response, SOP RPR-803, *Sampling Equipment Decontamination,* August 2013

16.2 Guidance Documents or other special references

16.2.1 U.S. Atomic Energy Commission Regulatory Guide 1.86, *Termination of Operating Licenses for Nuclear Reactors.* June 1974.

16.2.2 CH2M Hill Plateau Remediation Company, PRC-PRO-RP-40067, *Personnel and Personal Effects Decontamination.* September 10, 2009.

17.0 APPENDICES

17.1 Surface Contamination Values

APPENDIX 17.1

SURFACE CONTAMINATION VALUES

Recommended Action Levels for Removable Surface Contamination[a]

	Type of Radioactive Material[b]								
	Alpha Emitters			Beta or Gamma Emitters			Low Risk Beta or Gamma Emitters		
Types of Surfaces	$\mu Ci/cm^2$	$dpm/100cm^2$	cpm[c]	$\mu Ci/cm^2$	$dpm/100cm^2$	cpm[c]	$\mu Ci/cm^2$	$dpm/100cm^2$	cpm[c]
1. Unrestricted Areas	10^{-7}	22	1	10^{-6}	220	5	10^{-5}	2200	50
2. Restricted Areas	10^{-6}	220	4	10^{-5}	2200	50	10^{-4}	22000	500
3. Personal clothing worn outside restricted areas	10^{-7}	22	1	10^{-6}	220	5	10^{-5}	2200	50
4. Protective clothing worn only in restricted areas	10^{-6}	220	4	10^{-5}	2200	50	10^{-4}	22000	500
5. Skin	10^{-6}	220	4	10^{-6}	220	5	10^{-5}	2200	50

[a] Averaging is acceptable over nonliving areas of up to $300cm^2$ or, for floors, walls, and ceiling, $100cm^2$. Averaging is also acceptable over $100cm^2$ for skin or, for the hands, over the whole area of the hand, nominally $300cm^2$.

[b]Beta or Gamma emitter values are applicable for all beta or gamma emitters other than those considered low risk. Low-risk nuclides include C-14, H-3, Tc-99m, and other whose beta energies are less than 0.2 MeV maximum, whose gamma emission is less than 0.1 R/hr at 1 meter per curie, and whose permissible concentration in air (see 10 CFR Part 20, Appendix B, Table 1) is greater than 10^{-6} $\mu Ci/ml$.

[c]The values listed in units of cpm only apply for the $12cm^2$ active area of a specific 44-9 detector whose efficiencies for Pu-239 is 14% and whose efficiencies for Sr/Y-90 is 20%. The corrected cpm must be calculated individually for each radionuclide for each specific detector. The cpm values cannot be applied for any 44-9 detector or any other detector. The user must correct for the efficiency of the radionuclide for each specific detector used. See section 12.1 of this SOP for calculations of cpm.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
NATIONAL CENTER FOR RADIATION FIELD OPERATIONS
4220 SOUTH MARYLAND PARKWAY, BLDG C
LAS VEGAS, NV 89119-7533

OFFICE OF AIR AND RADIATION

MEMORANDUM FOR THE RECORD

DATE: March 14, 2013

SUBJECT: Reorganization Quality "Bridge"

FROM: Alejandra Baer, NCRFO Quality Assurance Manager

THRU: Ron Fraass, NCRFO Director 15 March 2013

TO: All NCRFO Staff

The purpose of this memorandum is to document the impact of the [former] Radiation and Indoor Environments National Laboratory (R&IENL) reorganization on the Quality System. Effective January 27, 2013 the reorganization occurred and R&IENL became the National Center for Radiation Field Operations (NCRFO). Effective immediately, the following must be implemented:

Background

R&IENL consisted of three (3) centers: the Center for Environmental Restoration, Monitoring and Emergency Response (CERMER); the Center for Indoor Environments (CIE); and the Center for Radioanalysis and Quality Assurance (CRQA). The latter, CRQA, was decommissioned in the end of calendar year 2012. Mobile Environmental Radiation Laboratory (MERL) was transferred to CERMER (now it resides in CRPR). CIE consisted of activities such as the Radon and Gravimetric laboratories, and the Tribal Air Monitoring Support (TAMS) Center; CERMER activities consisted of servicing EPA and other Federal Agencies, States, and Tribes on routine radiological support and emergency response (ER) activities.

Reorganization

The purpose of the reorganization was to more effectively utilize ORIA resources, and create a Center of Excellence for field activities in Las Vegas, Nevada. During the reorganization, two centers were created within NCRFO: the Center for Radiation Preparedness and Response (CRPR) and the Center for Planning and Training (CPT). To date, the formal reorganization of functional positions has occurred and individual duties are in the process of being assigned in accordance with the reorganization. Please see Attachments A, B, C, and D for detailed specifics on: NCRFO's functional statement; and NCRFO's Immediate Office (IO), CPT and CRPR's functional descriptions. NCRFO's brief functional statement is:

"...the National Center provided direct and indirect field support and technical support to EPA, other Federal Agencies, States, and Tribes. ... The National Center applies specialized expertise to evaluate and assess sites contaminated with radioactive material."

The brief functional descriptions for CPT and CRPR are as follows:

CPT: "...CPT participates in ORIA's national strategic planning processes and leads the development of strategic and local planning documents, including field exercises; conducting outreach and communication to EPA Regions and others on Radiological Emergency Response Team (RERT) for planning purposes; and planning for personal readiness, to include developing and tracking of needed training and certifications for appropriate personnel, and management of personal protection equipment and respirators used during field exercises and incident response." The Acting Director is Emilio Braganza.

CRPR: "...CRPR serves as NCRFO's lead for providing technical consultation on radiological field operations and provides direct and indirect field support to EPA, other Federal Agencies, States, and Tribes. CRPR has the lead in managing and carrying out field responses and conducting field exercises. CRPR is an essential component of EPA's RERT with staff serving in key roles during an EPA response to radiological emergencies and accidents nationwide." The Acting Director is Roger Goodman.

Decommissioning of CRQA

This process consisted of transferring the Mobile Emergency Response Laboratory (MERL) activities to CRPR. Transfer includes outstanding Quality Action Reports: (QAR) #2012-01 initiated on 1/18/2012 for gamma sample preparation activities; and QAR 2010-01 initiated on 1/27/2010 for gamma analysis and instrument use and calibration activities. Additionally, the Mixed Analyte Performance Evaluation Program (MAPEP) Series 24, 25, and 26 were transferred to CRPR (with custody transferred to Suzanne Beimer).

SOPs were both transferred and rescinded as documented in the Memo (dated 2/25/2013) titled *Transfer and Rescission of CRQA Standard Operating Procedures*. In this memo, specific instructions were provided to the CRPR Director for assuming responsibility/custody of these procedures.

Radon and Gravimetric Laboratory Activities

Radon activities shall be transferred to the National Air and Radiation Environmental Laboratory (NAREL) in Montgomery, AL. Until NAREL has established this operation (SOPs developed and validated, systems stabilized, etc.) NCRFO will continue to operate those activities under the direction of Emilio Braganza. This transfer could take up to two (2) years. The Gravimetric activities could possibly transfer to a commercial laboratory in six (6) months.

Tribal Air Monitoring Support (TAMS) Center

The TAMS Center will organizationally fall under the NCRFO's Director and the Farshid Farsi will report directly to the NCRFO Director.

Quality Assurance Coordinators (QACs)

CIE and CERMER's QACs were Scott Faller, and Mark Sells, respectively. Upon reorganization, Mr. Faller and Mr. Sells were transferred to CRPR and CPT, respectively. Until further notice, Mark Sells will continue to function as the QAC for CRPR, and Scott Faller will continue to function as the QAC for activities related to the Radon and Gravimetric Laboratories. They are being held in their current QAC positions due to critical documents that are under development and review under their oversight.

Documentation

Effective immediately, any new documentation must include the appropriate NCRFO, CRPR, and CPT designation. The following terms will be considered synonymously until existing documentation (Quality

Management Plan, Quality Assurance Manuals, SOP RIE-101 and appropriate forms, etc.) undergoes future review/revision:

1. R&IENL → NCRFO
2. CERMER will be changed to CRPR or CPT dependent on the functional descriptions…see attached and refer to other supporting documentation as necessary (e.g., position descriptions, etc.), or management direction.

Data reporting must be updated to reflect the new organizational components; existing customers must be made aware of the reorganization and change in organization names through formal correspondence.

Standard Operating Procedures (SOPs)

Until further notice and pending revisions of RIE-101, SOPs for gravimetric and radon laboratory operations will continue to be designated as "CIE" and SOPs for emergency response and/or field operations will be designated as "RPR." As SOPs are developed for CPT activities, the QA Manager will generate a policy memo (to be included in RIE-101 upon revision) defining new designations. Upon revision of RIE-101, the new lab-wide SOP designation will become "RFO." Any lab-wide SOPs this point forward will be issued with this designation.

Electronic Quality Documents: P Drive

New folder designations will be consistent with the SOPs section (above). Current folder designations will be as follows:

R&IE or RIE → RFO
CER → CRPR
CIE → CIE
RERT → RERT

Attachments: A: NCRFO's Functional Statement
B: NCRFO Immediate Office Functional Description
C: CPT Functional Description
D: CRPR Functional Description

cc: Michael Flynn, ORIA Director
Mary Clark, ORIA QA Manager
John Griggs, NAREL Director
Mary Wisdom, NAREL QA Manager

Division: National Center for Radiation Field Operations
Office: Office of Radiation and Indoor Air
Headquarters Office: Office of Air and Radiation

ORGANIZATION HEAD: Ron Fraass, National Center Director

REPORTS TO: Mike Flynn, Office Director

FUNCTIONS:

NATIONAL CENTER FOR RADIATION FIELD OPERATIONS (NCRFO). As the lead in EPA for radiological field operations, the National Center provides direct and indirect field support and expert technical support to EPA Regions, Office of Solid Waste and Emergency Response, other Agency offices, and other Federal Agencies, States and Tribes. The National Center manages all of ORIA's field resources. The National Center applies specialized expertise to evaluate and assess sites contaminated with radioactive material. The National Center supports the Agency's Homeland Security mission and is prepared to respond to and assist in recovery from radiological events, in accordance with the National Response Framework (NRF). The National Center is an essential component of EPA's Radiological Emergency Response Team (RERT) and serves in key roles during EPA's response to radiological emergencies and accidents nationwide. The National Center serves in a lead coordination role for RERT field capabilities for preparedness planning and coordination along with the Office of Emergency Management (OEM), Regional Emergency Response programs, and the Agency's Special Teams. The National Center maintains expertise, capability and mobile systems to support communication needs of personnel in the field supporting site work and emergency deployments. The National Center also has the lead for managing, maintaining and deploying portable air monitoring systems in support of RadNet, the nation's only radiation monitoring system which is managed by EPA/ORIA. The National Center staff serves as senior technical subject matter experts and field monitors in the Federal Radiological Monitoring and Assessment Center (FRMAC) and it stands ready to be deployed. The National Center staff also provides training to EPA Staff, States/Local/Tribes and other Federal Agencies on field radiological emergency response operations, helping to ensure consistency in response capabilities. In partnership with Tribes and the grantee, the National Center operates the Tribal Air Monitoring Support (TAMS) Center, to assist Tribes to develop and maintain environmental program capacity through diverse training and technical assistance. The National Center coordinates appropriate field radiation support with the National Analytical Radiation Environmental Laboratory. The National Center disseminates its scientific information through oral presentations, technical reports, membership in professional groups and through partnerships with other agencies and environmental groups.

Functional Description
NCRFO Immediate Office

NCRFO's Immediate Office (IO) is responsible for supporting activities throughout the Center through coordination and integration of budget, human resources and scientific technical activities to support Center customers including ORIA's Headquarters Divisions, other EPA Offices, EPA Regions, States, Tribes, Federal Agencies and others.

IO staff support the agency's Homeland Security mission through its key responsibility within EPA for responding to and assisting in recovery from radiological events. IO staff are an essential component of EPA's Radiological Emergency Response Team (RERT) with staff serving in key roles during an EPA response to radiological emergencies and accidents nationwide.

IO staff manages NCRFO's operations in: resource management, human resource management, safety, health and environmental management, radiation safety, facility operations, security (personnel and physical), information technology, and acquisition management.

NCRFO's Tribal Air Monitoring Support (TAMS) Center is housed in the IO. TAMS has the lead in assisting Tribes in developing and maintaining environmental program capacity through diverse training and technical assistance. This critical work is accomplished in partnership with Tribes and the grantee, Northern Arizona University's Institute for Tribal Environmental Professionals.

Functional Description
Center for Planning & Training (CPT)

In leading the Planning function, CPT participates in ORIA's national strategic planning processes and leads the development of strategic and local planning documents, including field exercises; conducting outreach and communication to EPA Regions and others on RERT for planning purposes; and planning for personnel readiness, to include developing and tracking of needed training and certifications for appropriate personnel, and management of personal protection equipment and respirators used during field exercises and incident response.

In leading the Training function, CPT develops, in collaboration with CRPR, radiation training programs and field exercises for EPA staff, States/Locals/Tribes and other Federal Agencies on field radiological emergency response operations to ensure consistency in response capabilities; develops and reviews training plans; assesses and tracks training needs for RERT personnel; and shares responsibility for delivering internal and external training with CRPR.

CPT staff serve as members of the EPA's Radiological Emergency Response Team (RERT) during EPA's response to radiological emergencies and accidents nationwide and may serve as senior technical subject matter experts and field monitors in the Federal Radiological Monitoring and Assessment Center (FRMAC). In coordination with CRPR, CPT staff also provides direct and indirect field support to EPA Regions, the Office of Solid Waste and Emergency Response (OSWER), other agency offices, other Federal agencies, States and Tribes by providing specialized expertise to evaluate and assess sites contaminated with radioactive material.

Functional Description
Center for Radiation Preparedness & Response (CRPR)

In leading the Technical Services function, CRPR serves as NCRFO's lead for providing technical consultation on radiological field operations and provides direct and indirect field support to EPA Regions, the Office of Solid Waste and Emergency Response (OSWER), other agency offices, other Federal agencies, States and Tribes. CRPR has the lead in managing and carrying out field responses and conducting field exercises. CRPR is an essential component of EPA's Radiological Emergency Response Team (RERT) with staff serving in key roles during an EPA response to radiological emergencies and accidents nationwide. CRPR staff serves as senior technical subject matter experts and field monitors in the Federal Radiological Monitoring and Assessment Center (FRMAC). CRPR provides specialized expertise to evaluate and assess sites contaminated with radioactive material. CRPR supports CPT in the development of strategic and local plans for field radiological emergency response operations. CRPR also supports CPT in the planning and development of radiation training programs and field exercises for EPA staff, States/Locals/Tribes and other Federal Agencies on field radiological emergency response operations to ensure consistency in response capabilities. CRPR shares responsibility for delivering internal and external field operations training with CPT.

In leading the Field Equipment Management function, CRPR has the responsibility to manage, maintain and track all of ORIA's field radiation detection and sampling equipment. CRPR manages and operates NCRFO's mobile scanning assets, mobile environmental radiation laboratory (MERL) and mobile sample preparation laboratory system, which would be deployed in the event of a major nuclear or radiological incident or accident. CRPR has the lead for managing, maintaining and deploying ORIA's portable air monitoring systems in support of RadNet, the nation's only radiation monitoring system which is managed by EPA/ORIA. This critical work is accomplished in partnership with ORIA's Radiation Protection Division (RPD) and the National Analytical Radiation Environmental Laboratory (NAREL). CRPR coordinates appropriate field radiation support with NAREL, and many CRPR's activities are performed in partnership with other offices in EPA and other federal agencies including the Department of Homeland Security (DHS) and the Department of Energy (DOE).

Radiation and Indoor Environments National Laboratory

Quality Management Plan

Effective Date: May 7, 2012

Radiation and Indoor Environments National Laboratory
Office of Radiation and Indoor Air
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Revision History

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0	Richard A. Levy	Oct 14, 1994
1	James C. Benetti	Jan 8, 2004
2	Alejandra M. Baer	May 4, 2006
3	Alejandra M. Baer	Nov 21, 2011
4	Alejandra M. Baer	May 7, 2012

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Table of Contents

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1.0 INTRODUCTION

1.1 Purpose

This document describes the management structure, principles, and policies of the Radiation and Indoor Environments National Laboratory (R&IENL); hereafter, also referred to as the Laboratory. The purpose of the Quality Management Plan (QMP) is to ensure that work performed by R&IENL is done in a manner that assures results of demonstrably high quality appropriate for their intended purposes. This QMP describes the quality assurance (QA) policies and procedures that documents management and implementation of the quality system at R&IENL. R&IENL operates as a division (laboratory) of the EPA's Office of Radiation and Indoor Air (ORIA) and this QMP is issued under the umbrella of the ORIA QMP.

1.2 Background

The U.S. Environmental Protection Agency (EPA) requires accurate, reproducible, and defensible data to evaluate environmental conditions, to assess potential health hazards, and to ensure compliance with its orders and regulations. To achieve this, data must be of known and desired quality. Policies initiated by the Agency Administrator in 1979 require that all EPA laboratories, program offices, and regional offices participate in a centrally managed QA program. The Agency's policy and program requirements to implement the mandatory QA program are set forth in CIO 2105.0 (formerly EPA Order 5360.1 A2), dated May 5, 2000. The Order requires each EPA organization collecting or using environmental data to develop and implement a management system of QA and quality control (QC) to assure that the collected data are of the type and quality needed for EPA decisions.

Each EPA program office and laboratory must develop and maintain a centrally managed quality system which must include those monitoring and measurement efforts mandated or supported by EPA through regulations, grants, contracts, or other formal agreements. The Agency quality policy states that each EPA laboratory, regional office, and program office must prepare a QMP covering all intramural and extramural monitoring and measurement activities that generate and process data for Agency use. This document provides guidance, and defines the QA management philosophy, structure, policies, responsibilities, and procedures for R&IENL.

1.3 Organization and Functions

R&IENL consists of the Director's Office and three Centers:

- Center for Environmental Restoration, Monitoring, and Emergency Response (CERMER)
- Center for Indoor Environments (CIE)
- Center for Radioanalysis and Quality Assurance (CRQA)

1.3.1 Center for Environmental Restoration, Monitoring, and Emergency Response

CERMER engineers, installs, and maintains ground-based systems for measuring and monitoring the relative distribution, and transport of radioactive pollutants in the environment. CERMER also provides expertise and support during radiological events in accordance with the National Response Framework (NRF) and is responsible for support to the Laboratory's technical mission with field-focus. Support includes site evaluation and removal actions, and radiological hazard identification and mitigation. CERMER consults on water and air quality criteria, health and safety protocols, risk assessments from a radiological perspective, and assist in interpretation and evaluation of analytical data.

CERMER staff can provide technical assistance to various Regional Superfund Site Managers in the form of oversight of Superfund contractors and recommendations for technical direction to On Scene Coordinators (OSCs) on site investigations or verification of cleanups.

1.3.2 Center for Indoor Environments

The CIE provides laboratory support to ORIA's Indoor Environments (IE) programs. CIE also includes the Tribal Air Monitoring Support (TAMS) Center, currently a partnership between R&IENL and Northern Arizona University/Institute for Tribal Environmental Professionals (NAU/ITEP). NAU/ITEP (through a cooperative agreement) provides training and technical support to tribes. CIE provides limited particulate matter (PM) filter weighing analysis from CIE's Gravimetric Laboratory. Although the TAMS Center relationship between CIE and NAU/ITEP is a partnership, all data throughput generated by CIE is subject to CIE review; similarly with NAU/ITEP, All training and technical support is the responsibility of NAU/ITEP.

The Center's Radon Laboratory assures through QC checks that measurements and calibrations performed in the Laboratory are accurate and precise. The measurement data is used to improve the customer's overall ability to accurately measure radon and is an important component in the Agency's efforts to reduce the public's risk to radiation exposure from radon gas and its progeny. CIE staff: conduct QA exposures to support quality assurance activities for States, EPA Regional offices, industry, and local governments; perform radon measurements in support of Environmental Justice surveys; and conduct bi-annual radon gas and radon decay product inter-comparisons to support industry proficiency programs.

Staff verify performance of radon measurement and/or detection instruments and or systems in partnership with private proficiency programs, and support air quality investigations through an air sampler loan program

1.3.3 Center for Radioanalysis and Quality Assurance

CRQA operates the Laboratory's fixed and mobile radioanalytic laboratories. The radioanalytic laboratory maintains a variety of radioactive standards which are traceable to National Institute for Standards and Technology (NIST), and participates in a national Performance Evaluation program. In addition, CRQA staffs and maintains the analytical equipment in the Mobile Environmental Radiological Laboratory (MERL).

1.3.4 R&IENL Directors Office

The Director's Office staff is responsible for supporting activities throughout the Laboratory. This is done through coordination and staff integration which includes coordination of the R&IENL budget, human resources, and scientific technical activities to support the Laboratory customers including ORIA's Headquarter Divisions, other EPA Offices, EPA Regions, States, Tribes, Federal Agencies, and others. The R&IENL QA Manager reports directly to the R&IENL Director – hereafter, also referred to as the Director – and works with the R&IENL Center Directors and Center Quality Assurance Coordinators (QACs) to develop and implement the QMP.

1.4 R&IENL Mission and Function

The mission of the R&IENL is protection of the public and the environment by minimizing exposure to radiation and air pollutants through environmental measurements, applied technologies, and education. The Laboratory accomplishes this by providing innovative, practical, and effective technologies and services in the areas of: environmental restoration and cleanup; radiological emergency response; laboratory and field radioanalysis; tribal outreach; PM2.5 gravimetric services; and indoor environments.

The Laboratory provides support primarily to the Office of Air and Radiation's (OAR) ORIA, and the Regions. Other EPA customers include the Office of Air Quality and Planning Standards (OAQPS), OSWER, and EPA's ten Regional Air and Radiation Programs. The Laboratory also provides gravimetric support to tribes through CIE. In addition, R&IENL provides support to other Federal Agencies such as the Department of Energy (DOE).

R&IENL disseminates its scientific information through oral presentations, data analysis reports, technical reports, membership in professional groups, and through partnerships with other agencies and environmental groups. R&IENL is the lead field radiation component of ORIA, providing scientific and technical support services to EPA Headquarters on radiation and tribal environments issues.

2.0 MANAGEMENT AND ORGANIZATION

2.1 Management Policies and Goals

R&IENL management policies are based upon five goals:

1. Protect the environment and human health.
2. Compliance with Federal, State, and local laws and EPA policy requirements.
3. Quality of products and services through data defensibility.
4. Cost effectiveness.
5. Commitment to continuous improvement.

The safety of the public and R&IENL employees is a high priority. R&IENL management and staff are expected to plan ahead, and take necessary precautions prudent to protect themselves, their co-workers, and the public from the potential dangers associated with their work.

Management is responsible for assuring compliance with the law, Agency policy, and with the requirements set forth in this document. R&IENL employees are informed of policies, and share accountability with management for its implementation. R&IENL policies also cite and confer responsibility and accountability for additional policies and regulations imposed by other Federal agencies as they apply to the facility and operations.

R&IENL requires data of acceptable and defined quality. Verifiability, credibility and defensibility are essential aspects of total quality. To be verifiable, credible, and defensible, results must be produced by procedures in accordance with regulatory requirements, data integrity systems, and good scientific practices. These steps must be clearly and completely documented at every stage of the process as defined by the various R&IENL quality system guidance and procedure documents.

Resources must be used efficiently and effectively to achieve maximum results. Streamlined work processes allow resources to be used more productively. R&IENL assures this by making those changes necessary to improve effectiveness and efficiency without loss to data quality.

Continuous improvement is an integral part of R&IENL's success. R&IENL is committed through various tools such as transparency, documentation, staff training, feedback, and internal and external assessments of the quality system.

2.2 Management Principles

The management structure at R&IENL is hierarchal. Final authority resides with the Director. Managers below the Director have authority over their own organizational units. Managers bear primary responsibility for the quality of all products and services provided by their organizational unit. Every employee is responsible for his or her own work.

A manager may delegate limited authority to employees he or she supervises. Those employees may then act with the authority of the manager in the authorized areas and be held responsible for the work performed. Managers cannot delegate the authority to conduct annual performance appraisals of their workers; each employee is ultimately accountable only to his or her direct supervisor. Authority delegated to an employee is effective only if the manager supports the employee's actions and decisions.

When an employee is given responsibility for the work of others, the employee must also be delegated the authority to direct that work. Otherwise, it is ineffective to give an employee responsibility for any work

without accountability. Each employee is held accountable by his or her immediate supervisor. All supervisors must have knowledge and understanding of the work performed by their employees and must be able to evaluate its quality.

It is important that all employees take responsibility for their own work. Employees may be required to defend their work publicly, or to explain or interpret their results to the user of the data. Individuals are required to sign or initial and date their work to indicate that they accept the responsibility for it. Employees must not take credit for work performed by others. If a team or committee has been assigned duties, mechanisms should be established for reporting the performance of those duties, either to supervisors or to a wider audience, and for accepting responsibility for the team or committee's decisions and actions.

The roles of all R&IENL personnel must be clearly and unambiguously defined in terms of authority and responsibility. It is the duty of a manager to ensure that the roles of subordinates are well-defined and understood by the employee, and are clearly communicated to all other staff members. When interaction between organizational units is necessary, the managers of the units are responsible for communicating the proper methods and levels of interaction.

Whenever possible, more than one person shall be able to perform each technical and professional level task associated with production of data. Cross-training provides opportunities for professional growth and increases the probability that work will not be delayed due to personnel absences.

Whether or not cross-training has been completed for a particular job or task, the requirements of the task shall be completely documented in an SOP or a series of SOPs. Documentation should be concise, clear, and complete enough that, when called upon, another qualified and trained individual can perform the task described sufficiently well to produce valid results. Each manager has the responsibility for identifying persons to be cross-trained in each work area and for providing time and resources to complete the cross-training.

2.3 Quality Assurance Policy

Environmental data collected or produced by R&IENL must be of known quality and be both defensible and verifiable. The Laboratory staff and management recognize that the achievement of quality data depends upon an effective and consistent QA program. The implementation of the quality system is achieved through a team effort of the entire laboratory staff, from management to laboratory analysts.

Success of the Quality System program is achieved through planning, preparation, implementation, and management's demonstrated commitment to quality. R&IENL's Quality System requires that each task and project be carefully planned (involving staff relevant to the project prior to commencement of each project), performed, reviewed, and documented. All data collection and measurement activities must be performed under an appropriate QC system using appropriate data quality measures. All activities that affect the quality of the final results must be performed according to documented standard operating procedures by appropriately qualified and trained staff. R&IENL management will support the Laboratory's Quality System by planning and prioritizing the allocation of staff, equipment, training, facilities, and support funding resources to ensure a successful quality program is maintained. Resource needs will be identified by the R&IENL QA Management Team and included in the annual R&IENL Annual Operating Plan (Budget), and Quality Assurance Annual Report and Work Plan (QAARWP). Resource planning includes staff support, training, intra/extramural operational resources, travel, and laboratory investments that maintain and improve the quality of data produced at R&IENL.

The general considerations and objectives of the system are as follows:

- Sample integrity must be preserved.
- Proper approved standard operating procedures and methods must be followed. Procedures and routine analytical methods used for sample collection and analyses must be readily available and understood

by all staff using the procedures. Results generated must be evaluated to identify method weaknesses and detect needs for further staff training.

- Only qualified and trained personnel shall perform functions related to sample/data collection, sample analysis.
- Each measurement process must be in a state of statistical control when measurements are made.
- All field and analytical instrumentation, and support equipment must be in proper working order. Instrument performance, calibration, and proper maintenance must be documented.
- The overall program of calibration, verification, and validation of measuring equipment, standards, and reference materials is operated to ensure that measurements made by R&IENL are traceable to national or international standards, whenever possible.
- The precision and bias of analytical methods must be recorded and maintained on a continuing basis. Precision and bias data are monitored by using control charts to assess continuing performance and to detect trends.
- Raw data must be properly reduced and accurately transcribed to the proper reporting format. Various levels of data review from acquisition to the final report are incorporated to reduce the probability of mistakes.
- R&IENL operates under the Office of Research and Development's (Las Vegas, NV) Chemical Hygiene Plan for work performed at CHL.
- All of the above considerations must be documented to validate the quality of data.

2.4 Organization

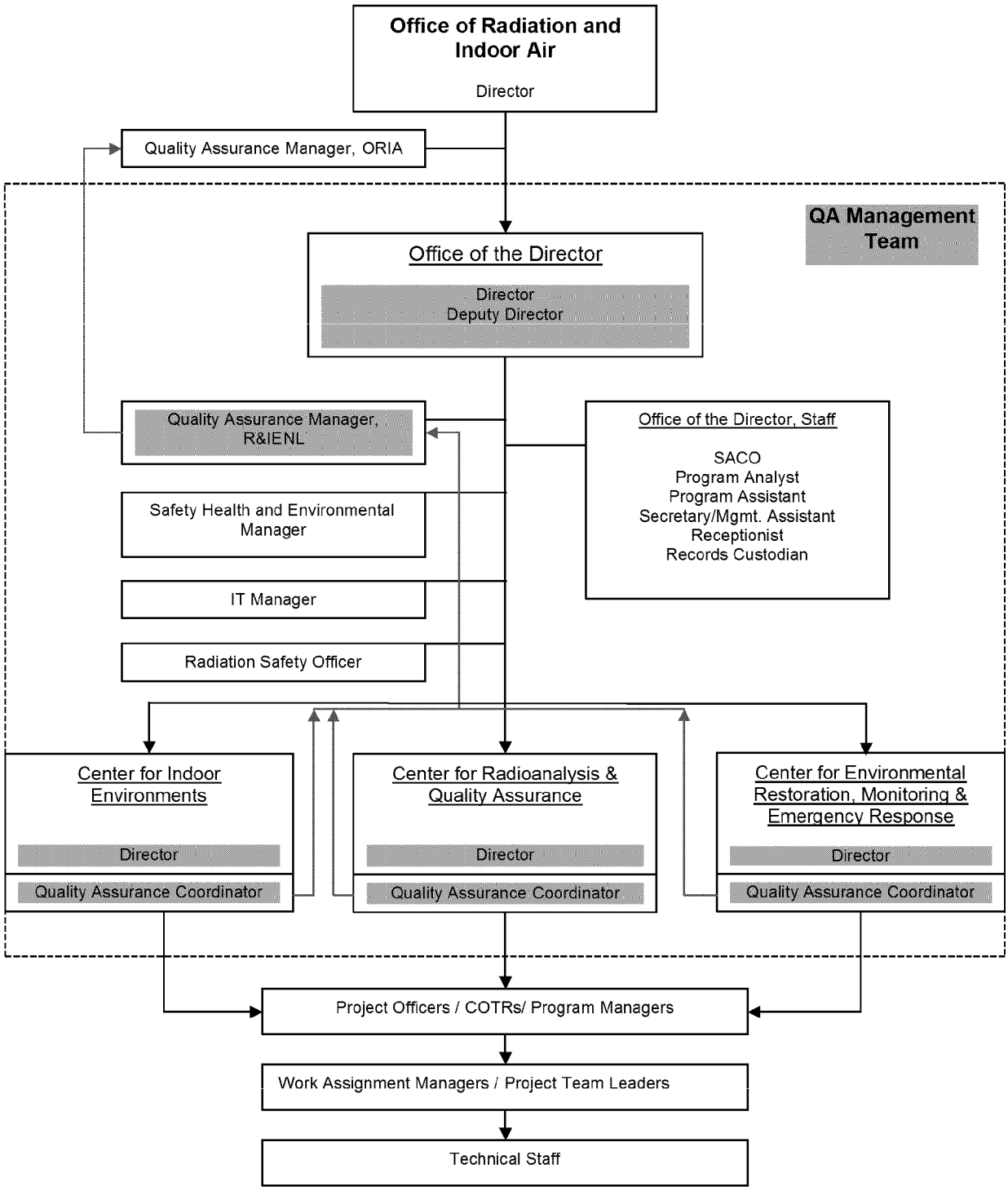
The R&IENL organizational chart (Figure 1) provides R&IENL's organizational flow, and identifies all of the components of the organization, and the organizational management positions, Quality Assurance Management Team (QAMT), program managers, and staff.

Each Center has a QAC who is responsible for implementation and management of the R&IENL QMP within their Center. The QAMT is comprised of the Director, Deputy Director, R&IENL QA Manager, R&IENL Center Directors, and their appointed QACs. The QA Management Team Lead is the R&IENL QA Manager. The relationship between the QA Manager and QACs is an independent open communication path which allows for the separation of management control from the Quality System information flow from R&IENL and to the ORIA QA Manager (designated by the red arrows).

The ORIA QA Manager implements the ORIA Quality System under the authority of the ORIA QMP. The R&IENL QA Manager implements the R&IENL Quality System under the authority of the R&IENL QMP (and consistent with the ORIA Quality System and QMP). The R&IENL QA Manager will maintain quality-related training records for the Laboratory.

The QA Management Team, which meets monthly, is the principle mechanism for ensuring that Quality System requirements and deficiencies are implemented and addressed, respectively. It is this team's responsibility to assure that all essential responsibilities of management, quality staff and ancillary staff having duties which impact quality of data are defined, understood and accepted. This approach ensures full and consistent Quality System implementation across the diversity of R&IENL activities.

Figure 1:
Quality System Management Organizational Chart for the Radiation and Indoor Environments National Laboratory



2.5 Roles and Responsibilities

The Director has the overall responsibility for the Quality System and its implementation. The responsibilities for developing, guiding and overseeing implementation of the R&IENL Quality System are delegated by the Director to the R&IENL QA Manager. This delegation includes all areas covered by the R&IENL QMP. The R&IENL QA Manager is located in the immediate office of the Director and acts independently of Center Directors. The Director approves the QMP and approves any delegation of QA Manager functions.

R&IENL Center Directors have primary responsibility for implementation of quality system requirements, quality of environmental data projects, and for the maintenance of the quality system within their area of responsibility.

To facilitate day-to-day implementation, guidance, and oversight of the quality system, each Center Director appoints a QAC in accordance with Section 2.6.4 of this document. The QACs maintain an independent path of communication to the R&IENL QA Manager. All quality related matters are communicated to both the QA Manager and Center Director. The QACs also work with project staff on quality system issues, and provide liaison to the R&IENL QA Manager through regular communication on all correspondence.

The Director, Deputy Director, R&IENL QA Manager, R&IENL Center Directors, and Center QACs together comprise the R&IENL QAMT which is the primary mechanism to ensure coordinated quality planning and implementation across the Laboratory's diverse Air and Radiation programs (see Section 3.3 R&IENL Quality Assurance Management Team).

To assure the successful implementation of the R&IENL Quality System, R&IENL program managers (in addition to their duties delegated to them by the Director) must work collaboratively with the QA Manager. Collaboration includes regular communication to assure matters related to quality are adequately addressed.

2.6 QA/QC Responsibilities of R&IENL Staff

This section defines the responsibilities assigned to R&IENL staff engaged in quality management, and scientific technical activities. Other specific roles and responsibilities, in addition to those defined in this section, are defined throughout this document.

2.6.1 The Director

The Director has the final authority and responsibility for QA and all other programs and activities at R&IENL. The Director has delegated authority and responsibility for oversight of R&IENL's Quality System to the QA Manager – this appointment is done formally via memorandum. The Director appoints the QA Manager. The QA Manager thus acts with the authority of the Director in all matters related to QA and can be overruled only by the Director. The Director also has final signature authority on all quality documents, data packages, and for start work on corrective actions. Formally (via memorandum) appoint the QAC

2.6.2 R&IENL Quality Assurance Manager

The QA Manager is selected based on criteria which includes, but is not limited to: a science background or BS degree; demonstrated knowledge of Agency and R&IENL quality requirements and policies; working knowledge of programs within R&IENL; and must possess the ability to effectively communicate verbally and in writing. The QA Manager has primary responsibility for the R&IENL quality system, quality issues, and the QA and QC programs – this includes revision of the QMP, and R&IENL-level SOPs. The QA Manager must maintain independence from all Laboratory operations which generate data. The QA Manager is responsible for guiding and directing staff in meeting the requirements of the Quality System, and serves as the primary QA contact within the Laboratory. All issues concerning QA/QC or programs and processes involving

data collection, use, interpretation, or evaluation at or for R&IENL must be reviewed and approved by the QA Manager. The QA Manager assists in planning and implementation of audits as requested by the Office of Environmental Information (OEI) Quality Staff (QS) and others.

The QA Manager develops, evaluates, and documents Quality program policy, guidelines, and procedures. The QA Manager also provides information and assistance on the QA program and in establishing QA requirements to management, analysts and other technical professional staff, and contract Work Assignment Managers (WAMs). The QA Manager monitors implementation of the QMP, and reviews and approves Quality Assurance Project Plans (QAPPs) and SOPs. The QA Manager develops Laboratory-wide quality related SOPs, policies, and guidelines. The QA Manager has specific duties outlined in the R&IENL Quality Assurance Manuals (QAMs) and R&IENL SOPs. These duties include the performance of technical and systems audits and inspections of laboratory records.

The QA Manager participates in the data review process by reviewing and signing each data package.

The QA Manager has the authority to stop work if there is a serious deficiency in any work process, and initiate corrective actions. The QA Manager may audit the work of any R&IENL staff as part of either an announced or unannounced inspection or audit process. The QA Manager stays abreast of new developments and policy changes.

The QA Manager conducts staff training on the Agency and R&IENL quality system(s), QA issues, documents, and policies; maintains records of audits, inspections, and corrective actions; reports regularly on QA issues to the Director, and prepares the QAARWP. The QA Manager participates in the annual management review of the Quality System, and serves as the lead member of the QAMT.

EPA Policy requires that resources be provided to allow the QA Manager to attend annual QA conferences and courses which provide training and updates on guidance documents, regulatory and methods changes, and other QA and QC issues.

2.6.3 Center Directors

The Center Directors have responsibility for implementing the Quality System requirements for all programs in their organizations which produce environmental data in accordance with EPA and R&IENL policies and procedures. Center Directors are also responsible for ensuring the development of QA/QC procedures and documentation for all technical operations under their supervision. A Center Director ensures adherence to approved SOPs, QAMs, QAPPs, QA/QC procedures and practices, and to other formal policies. He or she reviews and approves each QAPP submitted, and each QAM and SOP written or revised. The Center Director is responsible for assessing and identifying technical and quality training for staff. A Center Director may delegate authority for oversight of the Center's internal QA activities by the appointment of QAC for the Center. The Center Director is also responsible for development, approval, distribution and revision of appropriate QAMs for his or her Center, and for required and appropriate SOPs for all aspects of routine Center tasks and processes. Other Center Director duties include:

a. Overall responsibility for the technical operations within the Center;
b. Day-to-day supervision of laboratory or field operations including monitoring of performance in QC and QA;
c. Monitor the validity of the analyses performed and the data generated in the Laboratory or field to assure reliable data;
d. Formally (via memorandum) appoint the QAC (who has direct access to the QA Manager); and
e. Monitor and track the implementation and closeout of corrective actions in response to Corrective Action Reports (CARs, formerly referred to as Quality Action Reports).

2.6.4 Center Quality Assurance Coordinators

The Center QACs serve as the primary quality system contact and focal point within the Center and have direct access to the QA Manager. QACs are selected based on criteria which includes, but is not limited to: a science background or BS degree; demonstrated knowledge of Agency and R&IENL quality requirements and policies; working knowledge of programs within their respective Center; and must possess the ability to effectively communicate verbally and in writing. If the criteria cannot be satisfied, the Center Director must propose an alternate solution and implement a plan for achieving this in concurrence with the QAMT. The QACs have primary responsibility to:

a. Guide and assist technical staff in meeting the requirements of the QA program within their Center;
b. Monitor implementation of the R&IENL QMP, QAMs, and QAPPs in their Center;
c. Review, and concur (by signature with QA Manager) on QAPPs and SOPs;
d. Recommend Quality System related training and/or other requirements to the QA Manager or Center Director;
e. Assist contract, inter-agency agreement, grant, and cooperative agreement Project Officers (POs) and WAMs in the implementation of Quality System requirements in contracts, grants, cooperative agreements, Interagency Agreements (IAs), and work assignments supporting environmental data projects;
f. Assist the R&IENL QA Manager in the preparation of the R&IENL QAARWP;
g. Review and approve data reports before release; and
h. Ability to initiate a CAR.

If the Center Director elects to not appoint a QAC, then the Center Director assumes all of the QAC responsibilities.

2.6.5 R&IENL Staff

Staff that perform activities which affect data quality are vital elements in the quality system.

Every employee is responsible for the quality of his or her own work and identifying and reporting all conditions adverse to quality, using the appropriate reporting methods. Center Directors are responsible for the quality of work performed in their organizational units and have the authority to direct the work. WAMs and contract managers are responsible for monitoring the quality of work performed by contractors and for initiating any steps necessary to ensure that inadequate work does not continue.

Any employee may bring questions or concerns about technical issues, QA, QC, or health and safety directly to the attention of his or her Center Director, the QA Manager, the QAC, the Safety, Health, and Environmental Manager (SHEM), Radiation Safety Officer (RSO) or Director. Employees are expected to monitor their work processes continually for adherence to SOPs, good laboratory practices (GLP), health and safety regulations, and ways to make the work process more efficient and cost-effective. Employees are also responsible for obtaining adequate training and maintaining qualifications necessary to perform quality-affecting activities.

2.6.6 Program Managers/Officers

2.6.6.1 Radiation Safety Officer (RSO)

The RSO, appointed by the Director, is responsible for the implementation and enforcement of the radiation safety program. The RSO has direct access to the Director on matters of radiological safety and has the authority to immediately terminate any project that is found to be a threat to health, safety of personnel or potential contamination of critical property. The RSO reviews and approves SOPs or other quality

documents that describe activities covered by the Radiation Safety Manual (RSM). On radiation safety matters, the RSO speaks with the authority of the Director.

2.6.6.2 Safety, Health, and Environmental Manager (SHEM)

The SHEM, appointed by the Director, oversees the Health and Safety Program. The SHEM has direct access to the Director on matters of health and safety and has the authority to immediately terminate any project that is found to be a threat to health, safety of personnel or government property. He or she implements safety, health and environmental management systems to ensure that employees are furnished with a workplace free from recognized safety, health and environmental hazards; complies, with Federal/State/Local laws, rules and regulations as well as with EPA Safety, Health, and Environmental Management Program (SHEMP) requirements; ensures that employees are provided appropriate, timely SHEMP training; and ensures that employees comply with SHEMP program requirements, perform their assigned tasks in ways that protect their own safety and health, the safety and health of their fellow employees, and government property. The SHEM assures that all documentation, as they relate to health and safety are in place, and are reviewed annually or as needed (e.g., chemical hygiene plan); reviews and approves SOPs to assure that H&S requirements are met. On safety matters, the SHEM speaks with the authority of the Director.

2.6.6.3 Information Technology Manager (ITM)

The ITM, appointed by the Director, is responsible for ensuring the confidentially, integrity, and availability of R&IENL data. He or she ensures that operational procedures for data processing follow approved EPA and the Office of Information Resources Management (OIRM) policies, standards, and regulations.

2.6.6.4 Contracting Officer Technical Representative (COTR)

The COTR is sometimes called PO, or Contracting Officer Representatives (CORs). They are assigned by either the Center Director or Director (or his/her designee), and formally appointed by the contracting officer for that specific contract. CORs provide technical and program expertise to develop and manage contracts. CORs are considered part of the acquisition workforce and have authority only when such authority has been formally delegated by the Contracting Officer.

2.6.6.5 Work Assignment Manager (WAM)

The WAM, generally designated by the Director or Center Director, work on specific contract tasks under the COTR. WAMs are responsible for managing a project or contract and for the results of that project. They determine the criteria for quality based on the proposed use of project results. The WAM must ensure that adequate attention is given to QA and QC for all projects making environmentally related measurements. He or she establishes quality objectives and acceptance criteria for the project and assists with development of Data Quality Objectives (DQOs).

The WAM must ensure the development and implementation of appropriate QA/QC documentation such as QAPPs, SOPs, and record-keeping systems for extramural tasks. He or she will review and approve QA/QC documentation including the work plan, and ensure that QA, technical, and documentation requirements are met for the project. The WAM is responsible for oversight of contract activities and for adequate documentation of the project. The WAM initiates required corrective actions and appropriate documentation of CARs. The WAM works closely with the PM and may rely on one or more technical personnel for assistance. The WAM works closely with the QAC to

identify problems and required corrective actions, and to ensure that all applicable QA and QC policies and procedures are implemented and documented.

2.6.6.6 Records Custodian

Currently, R&IENL does not have a Records Custodian. However, as stated in Section 2.4 of this QMP, the R&IENL QA Manager maintains quality-related training records; sections 2.7, 3.1, and 3.2 describe how and where this QMP, R&IENL QAMs, QAPPs, and SOPs are maintained.

2.6.6.7 Funds Control Officer (FCO)

The FCO is responsible for ensuring that fiscal management operations of the Laboratory are conducted according to Agency policies and procedures. These include Document Control Number register, preparation and reconciliation of accounting reports, re-programming, project or resource needs, analysis and interpretation of fiscal data, intramural/extramural fund control and providing management advice and guidance regarding financial matters. The FCO advises the Director and Deputy Director in developing and managing budget resources, and provides oversight and coordination of the Laboratory's acquisition management program.

2.6.6.8 Simplified Acquisitions Contracting Officer (SACO)

The SACO is responsible for procuring items following all relevant EPA and R&IENL policies. The SACO is responsible for purchasing any quality-related item exactly as requested by the purchase originator. If the SACO finds a possible different source for the item, the SACO must confer with the technical staff member and receive approval for changing the purchase request before a change is made and before the purchase is completed. Quality-related items include, but are not limited to:

- measuring instruments
- calibration services
- standards and reference materials, chemical or radiochemical
- reagents
- particular types of support equipment
- computer hardware and software, especially database and analysis software and the Laboratory Information Management System (LIMS)
- environmental control systems

2.6.6.9 Project Officer (PO)

The PO is responsible for the oversight of grants, cooperative agreements, and IAs. The PO ensures the work performed meets/satisfies EPA and R&IENL quality policies such that a Quality Assurance Review Form (QARF) is completed for all work, and quality documentation is in place (e.g., QAPPs, Sampling Plans, etc.). The QARF must be reviewed and approved by the R&IENL QA Manager.

2.7 Implementation of the QMP

Once it is approved by the Center Directors, R&IENL QA Manager, the Director, and the ORIA Office Director and QA Manager, a copy of the new revision of the R&IENL QMP is distributed to each employee. At the time of distribution, each staff member must dispose of the previous version of the QMP. When changes to the QMP are substantive, the QA Manager schedules an all-hands meeting to introduce the QMP and review the guidance provided.

The R&IENL Quality System will be included in the orientation of all new R&IENL employees. Existing and new employees will receive instructions on where to obtain uncontrolled copies of the QMP, the appropriate QAM, and SOPs as applicable. Acknowledgement of receipt is required.

3.0 THE R&IENL QUALITY SYSTEM

Environmental data collected or produced by R&IENL must be quality data that is both defensible and verifiable. A fully implemented Quality System, meeting all EPA requirements, is integral to the success of R&IENL activities involving the collection of environmental data.

It is critical that all staff and management recognize the importance of an effective Quality System in achieving this goal. The primary purpose of the quality system is to ensure that all work done by R&IENL produces data of demonstrably high quality and is appropriate for its intended use. CIO 2105.0 requires that all EPA organizational units ensure that environmentally related data measurements are defensible and verifiable. The quality of data is known when all components are thoroughly documented, and documentation is both verifiable and defensible. All routine or planned projects or tasks must be undertaken with an adequate QAPP that specifies data quality goals.

Certain documents and activities are basic to the implementation of the Quality System.

- Preparation and annual update of a QAARWP based on guidelines established by the OEI Quality Staff and the ORIA QMP.

- Development and implementation of QAMs for each technical area of the Laboratory. The QAM(s) must present specific details and criteria for work processes including but not limited to such things as instrument QC, analytical and other process QC, software QC, analysis and evaluation of data, the system of peer review for documents, documentation and records, and corrective actions.

- Development, review, and approval of QAPPs for all projects and tasks in accordance with the Agency guidelines established by OEI Quality Staff and in accordance with the ORIA QMP and with R&IENL QAMs, SOPs, and policies.

- It is staffs responsibility to assure implementation of QA for all work produced under contracts and financial assistance agreements as specified in applicable EPA regulations, including subcontracts, grants, cooperative agreements, IAs, and sub-agreements, Memorandum of Understandings (MOU)s.

- Conducting audits (technical and management systems audits, etc.) on a scheduled basis of programs, activities, and projects which involve environmentally related measurements.

- Developing and adopting technical guidelines for estimating data quality in terms of precision, bias, representativeness, completeness, and comparability, as appropriate, and incorporating data quality requirements in all projects and tasks involving environmentally related measurements, collection, generation, evaluation, and use of environmental data by and for the Agency, or the design, construction, and operation of environmental technology by the Agency.

- Implementation and documentation of corrective actions, and incorporating this process into the management review.

- Assessment of appropriate training for all levels of QA management, to assure that QA responsibilities and requirements are understood at every stage of project implementation.

3.1 Documentation

The Quality System for R&IENL is presented in a series of formal documents which are reviewed annually, and revised when appropriate. These documents are:

- R&IENL's Quality Management Plan

- Quality Assurance Manual(s)
- Quality Assurance Project Plans
- Standard Operating Procedures
- Policies

3.1.1 R&IENL Quality Management Plan (QMP)

The QMP describes the Quality System in terms of the organizational structure, functional responsibilities of management and staff, lines of authority, and processes for planning, implementing, documenting, and assessing activities. The QMP is the umbrella document for management policies, goals, and processes which incorporate QA and QC into all aspects of R&IENL's work. The QMP describes how R&IENL implements its Quality System and educates its staff about QA and QC activities.

The Laboratory Director has primary responsibility for the QMP. The QA Manager has primary responsibility for review, compliance with the ORIA QMP, and distribution of the QMP. The document is reviewed annually by the QAMT, and final authority belongs to the Director. Each revision must be approved by the QA Manager, the Center Directors, and the Director. Once R&IENL approvals are completed, the document is accepted and will be implemented pending review and approval by the ORIA QA Manager and approval by the ORIA Office Director. The R&IENL QA Manager may approve changes that are minor in nature without ORIA approval. This includes correcting typographical errors, updating references and stated requirements based on revision of higher level documents, changing the name of an organization, and updating a documented local process to reflect improvements.

The QMP presents general goals, policies, and tools for the Quality System. Specific details about particular policies, procedures, and requirements are contained in other documents in the Quality System. These include QAMs, QAPPs, and SOPs. Interim policies, not yet formally presented in any of these documents, must be followed.

Contractors and grantees which are supported or funded by EPA are required by regulation to develop a quality system, and they are required to develop a QMP following EPA QA/R-2, *EPA Requirements for Quality Management Plans*. The QMP is the contractor's statement of the processes which will govern the QA and QC activities for the specific contractor. The QMP identifies the contractor's QA policies, criteria for the areas of applications, and definition of roles and responsibilities.

3.1.2 Quality Assurance Manual (QAM)

A QAM presents technical criteria for field, analytical, and administrative tasks to ensure that all data produced will be of known and desired quality, that all measurements performed by R&IENL are valid, scientifically defensible, and of known precision and accuracy, and that all processes, including evaluation and use of data, are correctly and completely documented and consistently implemented. There may be one or more QAM at R&IENL, each applying specific technical information and criteria to a particular program or area of the Laboratory. A QAM addresses all phases of the QC, QA, and quality assessment processes. Each manual presents specific and detailed information about tasks, processes, and criteria for specific programs and activities. A QAM provides a detailed program for evaluating QC procedures and assessing results produced by the Center or program.

The QAM will outline policies, procedures, criteria, and assessment tools applicable to the particular program or task.

The appropriate Center Director has the primary responsibility for the QAM(s) generated within their Center. Each revision must be reviewed and approved by the QA Manager, QAC, the Center Director, and the Director. It is appropriate [and helpful] to have other managers and staff review

the QAM drafts as well. Staff members must have access to the QAM under which they work and must receive training in the document. Each revision of each QAM must be reviewed at least annually by the Responsible Official (RO), QAC, the Center Director, and the QA Manager.

A QAM should contain information including, but not limited to, the following as appropriate for each Center, Office, or Program:

- Background, purpose, and objectives of the Center, Office, or Program.
- A description of staff, organization, and responsibilities in the Center, Office, or Program, and their specific responsibilities in the Quality System.
- An explanation of how personnel are trained in job-related tasks, QC processes, and safety policies; how needs for training are identified and fulfilled.
- Description of sample management procedures, chain-of-custody, documentation procedures, and tracking of samples and data.
- Description of procedures involved in making environmentally related measurements or other environmental data or environmental technology operations. This should include field sampling methods, writing and approval of work plans and QAPPs, sample/project acceptance, sample tracking, analytical methods, instrument calibrations, preventive maintenance, QC procedures and criteria, activities such as dose and risk assessment, data evaluation, data validation, data manipulations, data review, records control and retention, and corrective actions, as applicable to the Center, Office, or Program's tasks.
- Information on QA/QC as it applies to the Center, Office, or Program activities. This should include QA oversight, QAM and SOP use and revision, and audits and other assessments.
- Appropriate information on facilities and equipment, equipment maintenance (including preventive maintenance schedules), calibration and QC schedules, and materials/equipment/equipment maintenance procurement and control.
- Discussion of routine and appropriate health and safety measures and of environmental compliance measures such as waste disposal, and waste management as it applies to the R&IENL Environmental Management System.

Specific information required for each QAM varies with the tasks assigned to that Center Office, or Program. The QA Manager is the primary resource for information which must be contained in a particular QAM, and should be involved throughout the production and revision of a QAM.

3.1.3 Quality Assurance Project Plan (QAPP)

A QAPP describes in detail the necessary QA, QC, and other technical activities that must be implemented to ensure that the work performed on a specific project will satisfy the required performance criteria and objectives. Each project involving collection or production of environmental data conducted by R&IENL requires a QAPP unless the activities are fully described in a QAM. The requirement applies to all environmental programs funded by EPA that acquire, generate, or compile environmental data including work performed through contracts, work assignments, delivery orders, task orders, cooperative agreements, interagency agreements, etc.

The QAPP is required to ensure that the data collection, sample analysis, and sampling meet the required DQOs that have been established for the project. The content and level of detail is subject to the Agency's "graded approach" and will vary according to the nature of the work being

performed and the intended use of the data. The decision on the content and level of detail will be determined by the Center Director and PM, with concurrence from the QA Manager, and QAC.

No work shall be performed on the project until the QAPP is approved except under circumstances requiring immediate action to protect human health or the environment or operations conducted under police powers. A QAPP written by an R&IENL employee other than the QA Manager must be approved by the R&IENL QA Manager. A QAPP written by the QA Manager must be approved by the ORIA QA Manager.

EPA Requirements for Quality Assurance Project Plans (for all work performed by and on behalf of EPA), list the process and requirements for producing a QAPP. The QAPP must address, at a minimum, these elements:

- Project management: history and objectives, roles and responsibilities, and experimental design.
- Management of data acquisition: all aspects of measurement systems design and implementation, ensuring that appropriate methods for sampling, analysis, data handling, and QC are employed and are properly documented; sampling plans and procedures.
- Assessment and oversight: the activities for assessing the effectiveness of the implementation of the project and associated QA/QC, to ensure that the QAPP is implemented as prescribed; specific QC procedures, internal and external QC checks and frequency; performance of management and technical audits; procedures for corrective actions.
- Data validation and usability: the QA activities that occur after the data collection phase is completed; to ensure that the data conform to the specified criteria, thus achieving the project objectives; reporting systems.

Each QAPP shall contain procedures or reference to documents containing pertinent procedures to ensure comparability of data on the basis of consistency of reporting units, standardized data format, and adequacy of procedures utilized. A QAPP may, by reference, include material found in approved QAMs, SOPs, and policies.

3.1.4 Standard Operating Procedure (SOP)

SOPs contain specific details and procedures which help to ensure that data generated by their use will be of known and adequate quality. All SOPs must be developed, reviewed, approved, distributed, and revised in accordance with provisions in SOP RIE-101. An SOP details the method for an operation, analysis, or action, with thoroughly prescribed techniques and steps. The SOP must be sufficiently detailed that a qualified person can correctly perform the operation, analysis, or action with minimal additional help or explanation. SOPs are appropriate for routine and repetitive activities and shall represent a standard procedure or protocol which has been tested, and tests documented, and shown to lead to reproducible results under the conditions specified.

Staff have read-only access to current uncontrolled copies of all SOPs pertinent to their tasks, must be trained on the SOPs and training documented. As each revision of an SOP is approved, a distribution memorandum is submitted by the QAC to appropriate personnel and users. The memorandum contains the shared drive directory to the SOP in PDF form with appropriate disclaimers, as an uncontrolled copy. Any R&IENL employee can access the uncontrolled PDF copy of an SOP for personal use or to provide the document to those outside R&IENL who wish to use or reference the document.

Any new SOP must be authorized in advance by a Center Director, the QA Manager, or the Director. A number must be assigned by the QAC who maintains a log of current and rescinded SOP numbers. The Center Director or the Director also designates a RO for the SOP, who writes

or compiles and maintains the document. Each SOP revision must be reviewed and approved by the RO, the Technical Reviewer, the Center QAC, the Center Director, the QA Manager, and the Director. Other approvals may be required on a case-by-case basis. The SHEM, and RSO must review any SOP with health and safety, environmental management (e.g., waste minimization, waste disposal, or pollution prevention) or radiation safety ramifications. The QA Manager has responsibility for Laboratory-wide SOPs related to quality activities. Each SOP must be reviewed at least annually.

3.1.5 Policies

Policies must be clearly written and be as specific as practical. A written policy must be signed and dated by the responsible party. All policies at R&IENL must be written and clearly presented to all staff required to operate under the policy. Policies must be approved by the appropriate supervisor, the QA Manager, and/or the Director as applicable. Copies of formal policies must be maintained on the shared drive with direction to them/when policies are provided to staff via email. Copies of formal policies must be given to new employees, as applicable, as part of their initial orientation process. Paper copies are maintained in the Director's Office, and are posted on the shared drive.

3.1.6 Information Quality Guidelines (IQG)

EPA's document Information Quality Guidelines contains EPA's policy and procedural guidance for ensuring and maximizing the quality of information disseminated, and complements EPA's Quality Management System for assuring the quality of EPA's products and information. In addition to the Agency's IQG requirements, ORIA also implements product review through the ORIA Product Review Guidance document. Information that is adopted, endorsed, or used by EPA to support an Agency decision or position is generally considered "information" for the purposes of the IQG and is subject to pre-dissemination review in accordance with the Peer Review Handbook.

Information disseminated through the use of websites, must undergo review and approval for accuracy and to ensure consistency with quality policy and documentation.

3.2 The Document Control/Records Management System

R&IENL currently operates under a document control system for the production, review, revision, storage, and distribution of R&IENL quality documents (e.g., QMP, QAMs, QAPPs, SOPs). The procedures for SOPs are described in SOP RIE-101; otherwise, records are maintained in accordance with this QMP. Document control policies apply to printed internal documents that are maintained by or for R&IENL personnel. The most current version, in PDF, on the shared drive is termed as an uncontrolled copy. This is uncontrolled because the PDF documents(s) cannot be altered, and no controls are required/exist to prevent changes to this version.

The RO for each controlled document writes, compiles, maintains, or edits the original document and is required to review and, if necessary, revise the document annually. The RO also trains appropriate staff on the provisions of the document.

As each revision of a controlled document is approved and distributed to appropriate personnel, a PDF form of the document is posted on the shared drive. Any R&IENL employee can access the uncontrolled PDF copy of the document (read only) for use or to provide the document to those outside R&IENL who wish to use or reference the document. The controlled version of the document is maintained with the QA Manager and the Center QAC.

3.3 The Quality Assurance Management Team (QAMT)

The R&IENL QAMT is the principle mechanism employed by the Laboratory to develop, guide, implement, assess, and refine the R&IENL Quality System. The team consists of the QA Manager, Center QA Coordinators, the Director, Deputy Director, and Center Directors. The QAMT meets monthly, and more often in the form of focus subgroups, task forces, etc. as needed.

The QAMT serves first and foremost, to identify, prioritize, adapt and implement each of the required elements of an EPA Quality System applying the principle of graded approach. The QAMT is also the vehicle for assuring that each Center Director and QAC supports and implements the Quality System. The QAMT identifies quality-related training and orientation needs, assessment needs, adequacy of corrective actions, and needs for outreach to technical staff at R&IENL.

Any R&IENL staff member may submit a written request (to the QA Manager with a copy to the Center Director) to attend QAMT meetings and may submit issues of concern to the QA Manager. Requests must be submitted at least a week prior to the meeting. The request should clearly identify the topic and area of concern, explain its importance and/or consequences, suggest an approach to addressing the issue if possible, and identify action which may already have been taken. The QA Manager may decline the request with justification. The QA Manager also uses the QAMT meetings to inform the QAMT of QA policies, audit schedules and audit results, PT results, unusual project requirements, and other issues pertinent to the QA/QC program at R&IENL. When a particular question requires further study and action, the QAMT invites R&IENL staff to serve on a short-term workgroup to address the specific issue and bring recommendations to the QAMT.

3.4 Quality Assurance Reports to Management

3.4.1 Weekly Leadership Team Meetings

The QA Manager meets regularly with the Director and, upon request of the Director, participates in the weekly meetings to address QA or QC issues and related outstanding items. Regardless, quality is a standing agenda item in the Leadership Team meetings. On a routine basis, the QA Manager reports on audits and results of audits, PT results, and other QA and QC issues that require the attention of the Leadership Team.

3.4.2 Written Assessment Reports

When the QA Manager performs an internal audit, the QA Manager submits a written report of the audit findings and recommendations to the Director, the Deputy Director, and respective Center Directors and QACs. Responsible parties are required to investigate and correct deficiencies noted, and to submit a written audit response to the QA Manager.

3.4.3 Quality Assurance Annual Report and Work Plan (QAARWP)

The QAARWP is an EPA-required status report for the ending year and a plan of QA activities for the coming year. The report narrative includes information required from the EPA Manual for Environmental Programs. The QA Manager, with required input from the Director, Deputy Director, Center Directors, Quality Assurance Coordinators, and other appropriate personnel, prepares the QAARWP for submittal to the QA Manager at ORIA. The QA Manager requests input from directors in preparing the report, which cannot be completed without their input. The report is approved by the Director and then submitted to the ORIA QA Manager.

3.5 Technical Assessments, Audits, and Inspections

Technical assessments, audits, and inspections are intended to provide guidance for quality improvement, to identify problems and deficiencies, and to acknowledge what is being done well in R&IENL's operations. Audits are management tools for assessment and improvement, and are not to be viewed as punitive. Internal audits may be conducted either announced or unannounced by the QA Manager. Audit requests, to the QA Manager, must be done so in writing. However, staff members with quality concerns

may report them to the QA Manager or Lab Director and they will be offered the right to remain anonymous. It is the responsibility of the QA Manager to keep the QAMT abreast of audit reports/results during the monthly meetings.

3.5.1 Proficiency Testing and Cross-Check Programs

A PT or cross-check programs examine the ability of the Laboratory to perform analytical procedures and obtain data of known and required precision and accuracy. PT samples and cross-check programs are analyzed throughout the year as continual checks on accuracy and precision for all analyses. It is R&IENL goal to participate in as many PT and cross-check programs as practical.

At the time of this revision of the QMP, R&IENL participates in DOE's Mixed Analyte Performance Evaluation Program (MAPEP), and a PM2.5 round robin program with NAREL.

PT and cross-check samples must be analyzed and reviewed in the same manner as regular analytical samples. The QA Manager must be provided with copies of PT results received from external programs. Unacceptable results require an investigation and CAR. Written documentation of findings and corrective actions must be submitted to the QAC and QA Manager within the timeframe requested.

3.5.2 QA Manager Laboratory Audits

The QA Manager is expected to conduct at least one quality systems audit (QSA) during each fiscal year. The audits must be planned to cover all aspects of R&IENL's technical operations each year. The audit allows the QA Manager to assess the various components of the quality system and adherence to the QMP, QAMs, SOPs, generally accepted GLP, and written policies for R&IENL operations.

The annual internal audit is conducted by the QA Manager. The QA Manager may request technical assistance from staff members. The audit includes inspection of logbooks and other documentation kept by analytical or other staff, instrument maintenance logs, CAR files, and other documentation related to production and reporting of data. The audit also includes discussion with laboratory staff, questions about methods and SOPs, and surveillance of analysts and personnel as they perform tasks.

As part of the overall internal audit, the QA Manager will review any evidence of inappropriate actions or vulnerabilities related to data integrity. Discovery of potential issues is handled confidentially until such time as a follow-up evaluation, full investigation, or other actions have been completed. All investigations that result in finding of inappropriate activity will be documented by the Director or designee, and will include any disciplinary actions, corrective actions, and customer notification.

The QA Manager is required to provide documentation of the audit findings, deficiencies, and recommendations to the QAMT within one month after completion of an audit. Negative findings and deficiencies require initiation of a CAR and demand investigation and implementation of corrective actions by the appropriate personnel. Negative comments require a written response to the QA Manager within one month of the audit report, and completion and close-out of the related CAR in a timely manner.

3.5.3 QA Manager Field Audits

Analytical data can be only as good as the sample provided for analysis. Project requirements, sampling plans, collecting, preserving, and shipping of samples, and maintenance and use of equipment all affect the integrity of the sample submitted, as do the skill and experience of the

sampler. QAPPs must discuss in detail the planning and implementation of sample collection and handling and must reference approved and written methods for sample collection and handling.

The QA Manager will be involved during the entire life of a project. QA staff (QA Manager and QACs) will conduct field audits whenever feasible. The field audit will assess adherence to the QAPP and to any applicable QAM, SOP, or work plan. Maintenance and calibration of equipment, sampling plans, documentation and tracking, sample collection techniques, field screening procedures, field QC procedures, and preservation and shipping of samples will be examined.

When a field audit is performed, the QA Manager is required to provide documentation of the audit findings, deficiencies, and recommendations, to the QAMT within one month after completion of an audit. Findings and deficiencies require investigation and implementation of corrective actions by the appropriate personnel, and require a written response to the QA Manager within one month of the audit report.

3.5.4 Project Audits

When feasible, the QA Manager is expected to assess any project covered by a QAPP at least once during the life of a short-time project and at least every two years of a long-term project, and to provide written comments of findings to management. At the request of a work assignment manager, the QA Manager will assist in additional project audits. Such audits are expected to cover all aspects of a specific project from planning through close-out of the project.

3.5.5 The QA Staff Management Systems Review (MSR)

The QSA is part of an Agency-wide management assessment initiative. CIO 2105.0 (formerly EPA Order 5360.1 A2), Policy and Program Requirements for the Mandatory Agency-Wide Quality System, directs OEI to review and approve the implementation of quality systems across the Agency. The intent of the management assessment review process is to ensure that Agency decisions are based on environmental data of the type and quality necessary to support a particular decision or use. The audit, conducted once every three years by OEI Quality Staff, examines quality management policies, systems, and procedures, and the roles and responsibilities for each of the key elements of the quality system.

4.0 PERSONNEL QUALIFICATIONS AND TRAINING

4.1 Personnel Training

To ensure that personnel involved in field, technical, analytical, or other activities involving environmental data are able to carry out their duties, each employee is expected to undergo initial and continuing training as applicable. All training must be documented.

4.2 New Employee Orientation and Training

Each new employee must complete an orientation prior to commencement of work at R&IENL. The orientation includes specific information on personnel policies and a tour of the R&IENL facilities. Orientation includes a review of the job description and how the employee's position integrates with the overall organization.

Initial on-the-job training is conducted by the subject matter expert, or a qualified senior employee. This training involves familiarization with any applicable documents and policies pertinent to the employee's tasks.

It is ultimately the responsibility of the Center Director to identify the quality system documents which are necessary for each person to read, understand, and follow. The CD must identify these documents in a formal manner, through memo or signed form for each person stating the documents which he or she agrees

to read and comply with. The Director or Center Directors may delegate this responsibility. Normally, the supervisor for a new employee is expected to obtain all needed documents for the new employee prior to commencement of work.

4.3 Ethics and Data Integrity Training

R&IENL promotes EPA's core Principles of Scientific Integrity, first issued by the Administrator on November 24, 1999. Those principles are:

- **honesty** – EPA employees are responsible and accountable in all aspects of their science.
- **accuracy** – Employees represent their work, and the work of others, fairly and accurately.
- **responsibility** – Breaches of these principles must be promptly reported when discovered.
- **freedom from conflicts** – All science is conducted in an atmosphere free of conflicts of interest.
- **recognition** – The intellectual contributions of others are recognized and acknowledged.
- **knowledge of statutory authority** – Employees must know and understand the statutes and regulations that guide EPA's work.
- **open-mindedness** – Differing views and opinions on scientific and technical matters are a welcome part of the scientific process.

Any staff member who knowingly submits questionable data or alters, fabricates, or misrepresents measured data including QC data will be subject to disciplinary actions up to termination.

4.4 Safety and Environmental Management Training

It is the responsibility of management to provide opportunity and training for personnel to familiarize themselves with the safety rules, procedures, and equipment, so that accidental injury or damage to property does not occur. Personnel can prevent most accidents by using common sense, following safety guidelines, and asking questions when unsure. The purpose of safety training is to present the rules and policies in an organized manner and to point out some particular facility and laboratory hazards. Annual radiation safety training is also required as part of R&IENL's radioactive material license from the Nuclear Regulatory Commission (NRC).

The SHEM, and the RSO, with assistance from the Center Directors and Director, must annually assess individual needs for training in health and safety environmental management, and in radiological safety for each employee. Specific job responsibilities dictate the type, complexity, and frequency of such training. Once an employee is identified as requiring health and safety training, whether initial or refresher training, attendance and completion of the training are mandatory.

Members of the Radiological Emergency Response Team must receive adequate (e.g. demonstration of proficiency) training in procedures, use and maintenance of instrumentation and equipment, and use of personal protective equipment.

4.5 Quality Assurance Training

All personnel must receive annual training on the EPA and R&IENL quality systems and their implementation. All personnel working on projects involving environmental data must have appropriate training and experience in QA and QC concepts and operations. PMs, Center Directors, QA Manager, and the Director must have a working knowledge of Agency QA requirements and should be sufficiently familiar with laboratory and related measurement techniques to develop QAPPs, including data quality objectives. Analytical and other technical staff must have a thorough understanding of QA and QC as they

apply to environmental measurement activities, to the collection, manipulation, review, and reporting of laboratory data, and to interpretation of QC data.

Funds should be provided to allow the QA staff to attend annual QA conferences and training events. All training must be documented in the individual's training files.

4.6 SOP Training

Many tasks and processes at R&IENL are documented in SOPs. R&IENL policy requires that all employees whose work is covered by SOPs must be properly trained in the contents of the SOP. It is the responsibility of the Director, and Center Directors to identify which employees require training in each SOP pertinent to his or her area, to arrange for that training, and to provide documentation of the training to the QA Manager. New employees and employees new to a particular task must be trained on all procedures and SOPs, and demonstrate proficiency before they assume responsibility for any work covered in an SOP.

4.7 Information Technology Requirements and Training

Effort is made to ensure that employees have the hardware and software tools required for their specific tasks and are given adequate access to training in their use. When provided, staff is encouraged to attend training offered for new systems, new software, and revisions to software. In addition, all members of the staff are required to receive and complete training annually on Information Security, Physical Security, EPA's Limited Use of Government Computer Systems and Ethics. All training must be documented. The ITM annually reports on the status of Information Security Awareness Training to OAR IMO/ISO. This information is then reported to OEI.

4.8 Other Required Training

It is the responsibility of the Center Directors, supervisors, QA Manager, and the Director to identify other training required for an employee to successfully perform his or her assigned duties, to provide resources for that training, and to document that training. All training must be documented on the Personnel Training Needs Assessment form (P:\DO\Quality\Documents\Forms\Personnel Training Needs Assessment.docx) and records included in the employee's training records file.

4.9 Demonstration of Proficiency

Each field staff member, analyst, and staff must demonstrate proficiency in techniques/methods satisfactorily in accordance with respective QAMs. Staff who have successfully been performing an analytical procedure for a significant period of time before adoption of the SOP may be grandfathered at the discretion of the Center Director and the QA Manager. The grandfathering must be documented, signed, and dated by the staff member, QAC, Center Director, and QA Manager.

4.10 Training Records

Each employee is responsible for submitting training records to their Center Director after training is completed. It is the responsibility of the Center Director to assure staff have provided sufficient copies for QA Manager and Center record maintenance. The Center Director will submit original training records to the QA Manager, and maintain a copy for their files. Copies of training certificates will be provided by staff to the Center Director (or a CD-delegated official).

Personnel may be grandfathered with documentation by the Center Director stating qualifications and experience, and approval by both parties.

The ITM maintains an electronic file of training records for such mandatory training as IT security awareness training, and IT Continuity of Operations Plan (COOP) training.

5.0 PROCUREMENT

5.1 General

The Director is responsible for ensuring the Laboratory is properly maintained and equipped to support existing projects and programs. Subject to the limitations of the SACO's warrant, procurement is coordinated through the SACO and the Deputy Director and adheres to all Federal and EPA regulations, requirements, and guidelines, and to requirements of the Quality System for quality-related items.

5.2 Facilities and Equipment

The facility must be staffed and equipped to the extent possible to support existing programs. Such support capabilities must be evaluated and confirmed before acceptance of new projects. The facility and equipment must be maintained and operated in full compliance with appropriate QA and QC procedures, as well as health and safety requirements.

5.3 Procurement of Items and Services

All procurements are made following the requirements in the Federal and EPA acquisition regulations. The SHEM and RSO are notified when chemicals/reagents are procured for his/her approval. The RSO approves the orders for radioactive materials. A swipe/survey must be performed after receipt of radioactive materials by the RSO or designee, prior to distribution to respective individuals. The Center Director is responsible for review and approval of all orders of standards, tracers, and spike solutions before SHEM or RSO approval, and must notify the QA Manager via email prior to placing the order.

5.3.1 Authority

The authority to commit funds has been delegated to the Deputy Director and the FCO. The authority to obligate funds has been delegated to the SACO, subject to the limitations of the SACO's warrant. The SACO and the purchase card holders are the only employees authorized to obligate funds on behalf of the government.

5.3.2 Procurement of Contractor Services

R&IENL may procure environmental services from contractors where appropriate, including collection of environmental samples, procurement of laboratory analytical services, and analysis of environmental data. All procured items and services which directly affect the production and quality of environmental data must perform as specified in the procurement, and must:

- be acquired only as part of a procurement which includes QA requirements in both the initial award process and in the final contract,
- include specific documentation in the relevant work assignment(s) of conformance with QA requirements in the overall procurement,
- be developed or utilized only under an approved QAPP or QAM which provides specification of QA requirements and criteria for measuring performance, and
- be subject to monitoring, inspection, and objective evaluation of QA performance, audits of the supplier, and review and inspection of deliverables to assure acceptability and compliance with all QA requirements.

5.3.3 Procurement of Technical or Analytical Supplies, Materials, and Equipment

A vendor of technical or analytical supplies, materials, and equipment, including equipment maintenance, is an extension of the Laboratory. The standards for quality required of vendors are the same as those imposed on the Laboratory. The technical or analytical staff is responsible for requesting supplies, reagents, materials, and equipment of adequate quality (i.e., purity and reliability) to ensure that there will be no adverse effect on the technical or analytical data

produced. It is recognized, then, that it may be necessary for personnel to contact vendors for advance technical information before requisitions are prepared. However, no commitments may be made with vendors. Procurement officials shall not change or substitute procurement requirements without discussion and approval from the original requestor.

5.4 Ordering Procedures

The initial step in any procurement action is market research and acquisition planning with the SACO. The preparation of a Requisition in the EPA Acquisition System (EAS) follows. All requisitions must be approved by the Center Director, the Deputy Director, and the Funds Certifying Official before forwarding to the SACO. The SACO will determine the method to be used in securing the supplies or services requested.

Centers should make every effort to anticipate their needs, especially on items needed for day-to-day operations and order in sufficient quantities to hold rush orders to a minimum. Items will be grouped and orders consolidated to effect cost savings and/or reduce administrative burden.

5.5 Purchase Cards

Purchase cards are government credit cards issued to federal employees. An employee must complete a purchase card training course before being issued a purchase card. Requests must be approved by the appropriate Center Director and Deputy Director. The designated Approving Officials (AOs) for R&IENL are the Deputy Director and the FCO. Cardholders shall obtain written approval from their Center Director prior to purchasing any single item over $100. Procurement authority for the holder of a purchase card is $3000 for any one purchase ($2,500 for services). Each cardholder has a monthly spending limit. All quality requirements for purchase of supplies, materials, and equipment apply when making purchase card purchases. Purchase card holders are required to provide a weekly log of expenses and purchases to the AO.

5.6 Special Procurement Approval Requirements

R&IENL procures some items that require special approvals before the SACO can proceed with the procurement request. Special approval is required for the following:

- Information technology hardware and software – The ITM must review and approve any procurement requests for hardware or software. All requests for procurement of information technology equipment or software, including that attached to or part of laboratory analytical systems, must be processed through the ITM to ensure it conforms to EPA policies and standards.

- Chemicals - The SHEM must approve by signature any procurement request for chemicals. The appropriate analyst must be consulted and approve before any change is made in vendors or grades of chemicals ordered. Initial Center Director approval is required for all orders of standards, tracers, and spike solutions before SHEM agreement.

- Radioactive sources - The RSO must approve any purchase of radioactive materials to ensure that R&IENL complies with the limitations of its NRC license. The Center Director shall approve all orders of standards, tracers, and spike solutions before RSO approval.

- Quality-related items – The technical staff must request procurement of appropriate supplies and equipment and must agree with the SACO before any change in the purchase request is made.

5.7 Inspection and Approval

Technical staff who receive chemicals, radioactive standards, reagents, and other supplies and equipment which are quality-related items are **required** to inspect items received, and to verify that they comply with

specified requirements. Compliance verification must be documented by technical staff and submitted to the SACO. This documentation is maintained with the SACO records.

When purchased items are received in the Laboratory, the receipt must be confirmed by the requestor or an independent third party (someone other than the SACO or the purchaser of the item). The packing slip should be initialed and dated and given to the purchase card holder for their records that the items were received. The government will be invoiced for items/services not purchased with a purchase card. Requesters of these items/services are required to approve invoices for payment.

6.0 DOCUMENTS AND RECORDS

All records at R&IENL are expected to be clear, complete, and concise. Documentation must contain all pertinent information and records must be maintained in such a manner that they can withstand challenges as to the validity, accuracy, or legibility of their contents. All records and documents at R&IENL are public records except for those expressly included under the Privacy Act (5 U.S.C., §552a).

6.1 The Document Control System

R&IENL operates under a document control system. The policies and procedures for the production, review, revision, storage and distribution of documents are currently documented in SOP RIE-101.

6.2 Field and Laboratory Logbooks

Laboratory logbooks provide documentation of analyses, calibrations, field work, and other steps which are part of a complete and verifiable analytical record. A field logbook provides documentation of field equipment calibration and use, sample collection, shipping, and other details of a field effort. All observations shall be documented from departure of R&IENL until return. Logbook entries include all deviations due to conditions different than expected. Corrections are made drawing a single line through the error (so that the entry is still legible), including a signature or initials, and date.

All technical and other professional staff is expected to provide documentation which is complete, clear, and concise for all steps in a technical process, field operation, or project. Logbooks should contain sufficient information that the process documented can readily be reconstructed by a knowledgeable person. All logbook entries must be made in a timely manner (e.g., when it occurred not afterward). Information and data shall not be written elsewhere for later transcription into a logbook; however, under limited conditions and with prior approval from the Center Director can this occur. An analytical, technical, or field logbook is always subject to inspection by managers, the QA Staff, and auditors.

6.3 Raw Data, Calculations, and Data Manipulations

Raw data, logbook entries, instrument printouts, and bench sheets are all part of the complete data process for a field or analytical procedure. Enough information must be recorded that calculations can be verified, data manipulation can be traced, and the steps between collection of raw data and the final report can readily be reconstructed.

6.4 Records Management

All records pertaining to environmentally related measurements and all documents relating to the Quality System will be archived, retained, and disposed of according to the pertinent EPA records schedule. Quality System records, including logbooks which are complete, are archived with the QA Manager.

6.5 Correspondence

R&IENL follows the EPA Correspondence Manual 1320, 2011, which provides guidelines for preparing correspondence. The Manual specifies the policies, standards, and formats to be used by anyone who

writes, edits, reviews, signs, types, or controls correspondence Agency-wide. This Manual is available on the EPA Intranet.

6.6 E-Mail Retention

Electronic mail (e-mail) includes messages transmitted over any electronic mail communications system, whether implemented on a mainframe computer, local area network (LAN), or other platform. E-mail creators must decide whether a particular message is appropriate for preservation, i.e., whether the message documents Agency policies, programs, or activities.

All government employees and contractors are required by the Federal Records Act (FRA) to make and preserve records which document the organization, functions, policies, decisions, procedures, and essential transactions of the Agency. In addition, Federal regulations provide that these records must be properly stored and preserved, available for retrieval, and subject to appropriate approved disposition schedules. Personal material is not subject to EPA's records disposition schedules. If an electronic mail message meets the definition of a record under the FRA, it is required to be retained in accordance with EPA records disposition schedules.

Electronic mail messages may also constitute as agency records under the Freedom of Information Act (FOIA). If an electronic mail message is an agency record for FOIA purposes, it must be disclosed where responsive to a FOIA request, unless protected from disclosure under a FOIA exemption. E-mails identified as records must be stored according to the Enterprise Content Management System (ECMS) guidelines.

The general policy in defining a record for preservation is that:

- the message was "made or received by an agency of the United States Government under Federal law or in connection with the transaction of public business," and

- the message was "preserved or appropriate for preservation by that agency . . . as evidence of the agency's organization, functions, policies, decisions, procedures, operations, or other activities of the Government or because of the informational value of data in it."

6.7 Records Preservation

Examples of e-mail and other records that should be preserved include:

- records that document the formulation and execution of basic policies and decisions and the taking of necessary actions;
- records that document important meetings;
- records that facilitate action by agency officials and their successors in office; and
- records that make possible a proper scrutiny by the Congress or other duly authorized agencies of the Government; and records that protect the financial, legal and other rights of the Government and of persons directly affected by the Government's actions.

7.0 COMPUTER HARDWARE AND SOFTWARE

R&IENL uses information technology (computer hardware and software) to improve the quality of its results and the efficiency of its work processes. Since the quality of the computerized systems directly affects the quality of results, a sturdy information technology system QA program is essential. All information systems at R&IENL are governed by Federal law, rules, and policies and conform to EPA guidance.

7.1 Roles and Responsibilities

Important roles in the management of R&IENL information technology hardware and software include the ITM, the Server Administrator, the Telecommunications Administrator, Database Administrator (DBA),

Analytical System Technician, and Application Developer. An employee may act in more than one of these roles.

7.1.1 The Information Technology Manager

The ITM is responsible for ensuring that R&IENL's information technology (voice and data) systems are in compliance with federal and EPA policies and regulations. He or she serves as the Information Security Officer (ISO), coordinates the overall computer and voice processing directions of the Laboratory, ensures all computer-related procurements meet EPA specifications, and coordinates all matters of information technology with the EPA's OEI, OAR, and Office of Acquisition and Resource Management (OARM) as appropriate.

The ITM is responsible for ensuring that R&IENL's internally written applications adhere to all federal and EPA regulations and that these applications are properly planned, reviewed, implemented, tested, and documented prior to use. He or she works to ensure the confidentiality, integrity and availability of R&IENL data, authorizes access to networks and data after coordination with Center Directors and the Director, and ensures information technology training and compliance for users and administrators.

7.1.2 Network Engineer and System Administrators have the following responsibilities:

- maintaining the R&IENL LAN;
- maintaining the DataNet LAN;
- maintaining the Radon and Gravimetric Laboratories Network;
- maintaining mobile/vehicle networks;
- maintaining interconnectivity of laboratory networks with the internet and EPA Wide Area Network (WAN), as appropriate;
- managing of the R&IENL's Telecommunications system and its interconnectivity with the public service telecommunications (PST) system;
- configure and maintain satellite communications, mobile servers/workstations to provide network infrastructure support for mobile vehicles;
- providing end-user support for the use of video conferencing, voice and other telecommunications equipment; and
- providing support for wireless communication capabilities including satellite radios, satellite phones, UHF/VHF/HF radios and repeaters, and multiple emergency response vehicles with self-contained Information Technology (IT) structures, cell phone contracts, Blackberries, and AAA tokens.

7.1.3 DBAs have the following responsibilities:

- oversee the operation of the Laboratory database; and
- coordinate with the ITM to ensure database function and synchronization with data recovery site.

7.1.4 Analytical System Technicians have the following responsibilities:

- day to day support for all analytical systems on DataNet, Radon and Gravimetric Laboratories Network, and all peripherals; and
- assist users with analytical software.

7.1.5 Application Developer (on-site) will:

- complete all application design requirements according to relevant EPA policies;
- complete the LIMS programming;
- provide support in training on EPA scientific and Radon/Gravimetric Laboratories hardware/software applications
- provide application updates as required; and

- provide application development/IT support for systems such as the scanner van, environmental Radiation Ground Scanning (ERGS) devices, Sample prep Trailer, Mobile Command Post and the MERL.

7.2 Data Processing Goals and Policies

R&IENL's first goal for data processing is to maintain the integrity and availability of the data in support of R&IENL operations, projects, and tasks. Operational procedures for data processing at R&IENL follow approved OEI and OARM policies, regulations, and standards.

All software installed on R&IENL computer systems connected to the network must comply with EPA policy and licensing laws. The use of other than approved software is forbidden. Automated periodic audits of desktop software are conducted to prevent and identify license and copyright violations. Only software approved by OEI for the R&IENL LAN and the ITM for DataNet and Radon and Gravimetric Laboratories is authorized for installation on the respective networks. Any other software will require ITM approval prior to installation.

A list of all approved software used on R&IENL's DataNet to support normal operations is maintained by the ITM, and is available upon request. The approved software for R&IENL LAN (EPA WAN) is maintained by OEI.

All data on servers are backed up nightly. No EPA data are authorized for storage on local desktops. Backup tapes are preserved for a period of at least one year. DataNet data is synced, every 30 minutes, to the COOP location at NAREL The R&IENL shared drive (P) is synced once daily to the COOP location at NAREL. The R&IENL LAN is backed up daily on the local network servers.

R&IENL desktop power management for all networks will be in compliance with EPA's Electronic Stewardship Policy. Analytical systems will be handled as recommended by the vendor. Anti-virus software is run automatically on all government desktop computers. No personally owned equipment and peripherals will be allowed to be connected to DataNet and R&IENL (EPA LAN) network unless access is through the EPA's approved remote access capability.

Computer software procured or developed in-house must be documented in a manner appropriate to the application or task in which it is used. Each new application written and implemented for R&IENL which will have many users or which will have an impact on data quality requires a design proposal with detailed functional description and a full review and testing prior to implementation. Potential users must review and approve the design proposal before the software is written. The user must review, approve, and document all stages of the software implementation and testing.

Non-commercial software developed specifically for R&IENL by another organization including contractors, and which will be used for environmentally related measurements must be delivered with complete source code and adequate documentation, including a user's manual and a programmer's manual. Both the source code and the documentation must be provided in accordance with Office of Acquisition Management (OAM) policy. Any software developed must initially be requested, in writing, to the IT Manager with a design proposal (as identified above). The software requires thorough testing plans by both the developer and the requestor, which must be approved by the IT Manager, the Center Director, the QAC, and the QA Manager. The testing plans must show that the software is being tested against the original specifications. The developer and requestor must provide a written certification that the software was tested according to the plan, along with a narrative of any problems encountered during testing. Documentation package that includes the design request, approved testing plan(s), written certification of approval, etc. must be maintained by the appropriate Center QAC.

Such software systems include, but are not limited to, environmental data bases, and systems used for sample analysis, process control, data analysis, and dose and risk assessment. The source code and documentation should be adequate to allow R&IENL programmers to maintain and enhance the system. Both the source code and the documentation must be provided in computer-readable form.

The ITM is required by policy to maintain a record of all non-commercial software development and subsequent modifications.

The ITM must approve the purchase of all software and hardware items and/or systems prior to procurement as per OAR policy.

Whenever feasible, data collection instruments should be directly connected to R&IENL computer systems and raw data should be captured and processed electronically with minimal data entry by operators. Qualified personnel must still review the data before and after they are stored in R&IENL data bases. Double entry should be used whenever appropriate to minimize data entry errors in data base systems and analytical software. Bar codes should also be used if their use is both cost-effective and practical.

Routine maintenance of information systems will be based on specific network needs. Server maintenance will be scheduled monthly on a Friday to minimize disruption to the Laboratory. Desktop maintenance on the R&IENL systems (EPA LAN) is conducted by OEI for Customer Technology Services (CTS) users and R&IENL's IT Team for non-CTS users. When possible, all routine work done on DataNet and Radon and Gravimetric Laboratories Network will be preceded by an email that includes the expected time to return to operational status. Exceptions to this policy include incidences of equipment failure or direction from ORIA and above to take immediate action. The IT Manager will attempt to minimize the disruption to laboratory functions whenever possible.

8.0 QUALITY ASSURANCE PLANNING

8.1 Purpose

The purpose of QA planning is to document how individual data operations will be planned within the organization to ensure that data or information collected are of the needed and expected quality for their intended use.

8.2 Project Planning

It is the responsibility of the Center Director to initiate the QA planning process for a project, task, or program. Quality staff members and others with particular expertise should be involved in the planning process from the beginning to assure the effectiveness of the planning and success of the project occurs.

The planning process for a project or program other than routine work which is described in a QAM should ensure that all organizations and parties who contribute to the quality of the environmental program results are identified and that they participate in the process. The planning process must include direct communication between the customer and the supplier of data to ensure that there is a clear documented understanding by all participants of the needs and expectations of the customer and the product or results to be provided by the supplier.

Planning for non-routine work must fundamentally be geared to the delivery of acceptable quality. All projects which involve the production and/or use of environmental data should be planned using the DQO or similar process. The results of the planning effort must be documented in a QAPP and approved for implementation. The DQO process and the QAPP are important tools which help to ensure that quality is a fundamental part of the work process. Implementation of the project must be in conformance with the QAPP. Deviations must be approved and documented by the QA Manager, and in many cases require corrective action.

Each project plan should include steps to assure the production of scientifically valid data. The quality of the data is expressed as DQOs in terms of the acceptable rates of decision error for the intended use of the data. The data shall be defensible, of known precision and accuracy, of acceptable completeness, and in a form suitable for comparison with other measurement data and with regulatory requirements. To the extent possible, the acceptable numerical limits on data error should be derived using statistical procedures.

8.3 DQO Process

DQOs are qualitative and quantitative statements derived from the DQO process or other systematic planning approach that clarify study objectives, define the appropriate type of data, and specify tolerable levels of potential decision errors that will be used as the basis for establishing the quality and quantity of data needed to support decisions. They in part represent an analytical statement of the tolerable error in a sampling or analysis program. They are established through a process involving the technical and management staff, and must be made on the basis of requirements for acceptability and reliability of the data balanced against the resources available. The process involves consideration of factors including the type of data sought, available technology, cost, resource requirements, level of uncertainty, and sampling design. The effort put into the DQO process should parallel the significance and magnitude of the project. The DQO process involves seven steps:

1. State the problem - Define the problem that necessitates the study; identify the planning team, examine budget, schedule.

2. Identify the goal of the study - State how environmental data will be used in meeting objectives and solving the problem, identify study questions, define alternative outcomes.

3. Identify information inputs - Identify data and information needed to answer study questions.

4. Define the boundaries of the study - Specify the target population and characteristics of interest, define special and temporal limits, scale of inference.

5. Develop the analytic approach - Define the parameter of interest, specify the type of inference, and develop the logic for drawing conclusions from findings. Choose either decision making (hypothesis testing) or estimation and other analytic approaches.

6. Specify performance or acceptance criteria - For the decision making model, specify probability limits for false rejection and false acceptance decision errors. For other analytic approaches, develop performance criteria for new data being collected or acceptable criteria for existing data being considered for use.

7. Develop the plan for obtaining data - Select the resource-effective sampling and analysis plan that meets the performance criteria.

The DQOs should specify the details of the data required, including detection limits, accuracy, and precision, the calculation methods to be used, the presentation of results, and the acceptable level of confidence or acceptable level of uncertainty of the results for the stated objectives. The DQOs must address the completeness and representativeness of the data in the context of the overall or total measurement, and describe deviations or lack of information for all parameters. Goals for these factors should be defined before beginning actual measurements or data collection.

Criteria for acceptance are dictated by the intended use of the results. Development of a decision protocol to establish the statistical objectives of the program is a collaborative effort which balances various factors on a scientifically valid basis with appropriate consideration of the study objectives and acceptable costs. Development of DQOs involves technical considerations such as variations in environmental sampling methods and limitations in analytical sensitivity and similar factors.

EPA developed the DQO process to aid in the planning of environmental data collection activities. While the use is not mandatory, the DQO process provides for a systematic and graded approach to planning. The graded approach bases the level of QA/QC used on the nature of the work being done and the intended use of the results.

8.4 QAPP Requirements

A project which will generate environmental data or create or use environmental technology, and which is not fully described in a QAM, requires a QAPP. The content and level of detail in each QAPP will vary with the nature of the work being performed and the intended use of the data. The QAPP must provide sufficient detail to enable the QA Manager and others to judge the acceptability of the QAPP for the particular work or task. No work shall be performed on the project until the QAPP is approved, except in circumstances requiring immediate action to protect human health or operations conducted under police powers.

8.5 Documentation of the Planning Process

As with any task related to environmental data generation, collection and assessment, or environmental technology, the quality planning process should be documented in sufficient detail that basic information and decisions are easily understandable and the planning process can be reconstructed by a knowledgeable person. Planning and documentation commences with the customer request through formal reporting to the customer.

9.0 QUALITY IMPLEMENTATION OF WORK PROCESS

9.1 Roles and Responsibilities

9.1.1 The Director and Center Directors

The Director and Center Directors are responsible for the successful implementation of the quality system for all activities under their direction. This includes organizing and planning activities to meet quality objectives and requirements. They ensure that work performance and documents related to quality are reviewed as required per Section 3.0 of this document. They also assure that resources and time are available to properly train the staff to achieve and maintain QA proficiency.

9.1.2 The Quality Assurance Manager

All operations involved in obtaining or processing environmentally related measurements is monitored by the QA Manager. This includes involvement in the planning process, assessment of QA and QC processes, and technical and systems audits with documentation of findings. The QA Manager has the authority to stop work on any project based on concerns about the quality of the work. The QA Manager shall work with the Center Director and the Director to address any deficiencies that may compromise the quality of data. If after repeated efforts to correct deficiencies any remain unresolved, such as lack of support from R&IENL Management, then the QA Manager must report this to the ORIA QA Manager. The report must be in writing and contain a description of the deficiencies, the management activities, and the current status.

9.2 Implementation of Work Processes

All R&IENL environmental data collection, processing, and analysis operations will be implemented in accordance with approved QAMs, SOPs, and QAPPs developed in conformance with this QMP.

9.2.1 External Data Collection Activities

The ultimate goal of the EPA Quality System is to adequately support decisions that are based on environmental data collected by or for EPA. There must be adequate oversight of data collection activities. For programs where EPA funds are used by others in generating or collecting environmental data, organizations must meet QA requirements as specified in the EPA Acquisition Regulations (48 Code of Federal Regulations, Chapter 15, Part 1546). Additional details about these QA requirements, including a standardized QA review form for these projects, are given in the Agency's Contracts Management Manual.

9.2.2 Routine Sample Collection, Handling, and Analytical Activities

Each Center will have its own Project and Sample Acceptance Form which describes pertinent information required for correct sampling, including volume required for analyses, correct preservation and shipping procedures, and information on available analyses and usual detection limits. Sample collection must be conducted in accordance with approved QAPPs, QAMs, and SOPs and must be fully documented. Preservation, packing, and shipping of samples must be in accordance with all applicable health and safety policies, GLPs, and shipping and transportation regulations. Each step in the sample handling process must be completely documented.

Analysis of samples must be conducted in accordance with approved QAMs, QAPPs, SOPs, and written policies. Every step of a sampling handling procedure must be documented completely, clearly, and concisely.

10.0 QUALITY ASSESSMENT AND RESPONSE

Effective management requires continual assessment of data and the quality system. The assessment includes, but is not limited to, monitoring of processes, peer review, audits and inspections, corrective actions, etc. In all cases, the quality staff and others who conduct assessments are given sufficient authority, access to programs and managers, and organizational freedom to:

- review data at all stages of the analytical process to ensure that data reported to clients meet all QA and QC requirements;
- identify quality problems;
- identify and cite noteworthy practices that may be shared with others to improve the quality of their operations;
- propose recommendations for resolving quality problems; and
- independently confirm implementation and effectiveness of solutions.

10.1 Data Quality Assessment

Generated and processed data must be evaluated to determine whether the DQOs have been satisfied. The following steps ensure that adequate data quality will be obtained:

- The data from each project should be evaluated frequently during data collection to ensure that the planned measurements and the analytical results satisfy the objectives.
- Internal chain-of-custody procedures are required and must be followed.
- The values obtained on known reference or spiked samples must be compared with the known values and recorded. Specific guidance for evaluation of these samples is contained in the various R&IENL SOPs for analytical methods field instrument data and in the written QA policies.
- An independent review process must be used when reviewing data. Requirements are provided in Center specific QAMs and SOPs that describe generic review and approval procedures for data produced during field activities for routine and emergency situations.

10.2 Statistical Quality Control

The numerical quality indicators used to monitor the performance of measurement instruments and processes should have tolerances wide enough that corrective action is not required frequently because of random statistical variations in the value of the indicator but not so wide that real failures are not discovered. The quality indicator may be assumed to have a known statistical distribution, with warning

and rejection limits chosen using the principles of statistical hypothesis testing. Fixed warning and rejection limits may also be used if there is no practical justification for statistical tests.

10.3 Monitoring of QA and QC Data

The QA Manager is the focal point of all data generated in support of the QA program. This includes, but is not limited to results of PT and cross-checks, and documents related to the quality system. The QA Manager and QACs maintain comprehensive files related to the quality system.

10.4 Performance of Project Assessments and Reviews

The PM or WAM will review and assess the quality of the data and the overall QA effort of their project(s) to assure conformance with the QAPP on routine work. Contractors or grantees may be requested to demonstrate their ability to conduct the required technical or analytical tasks. This demonstration may include analysis of QC samples and PT samples. Audits of contractors and grantees should be made at least once during the period of the contract or grant and more often as deemed necessary and appropriate. A data quality assessment should be completed before data are accepted.

The QA Manager shall develop an annual plan for management, performance, and technical reviews and data quality audits.

10.5 Data Integrity

It is Agency policy to conduct all business with integrity and in an ethical manner. It is a basic and expected responsibility of each staff member, each manager, and all laboratory contractors, to hold to the highest ethical standard of professional conduct in the performance of all duties and to adhere to the EPA's Principles of Scientific Integrity.

Staff must notify the QA Manager and the Director if fraudulent practices are suspected, with the understanding that such reporting is encouraged and confidential. Center Directors or supervisors must immediately investigate the problem and document all findings and impacts or potential impacts on data or other information products, and determine the root cause of the problem.

11.0 QUALITY IMPROVEMENT AND CORRECTIVE ACTIONS

11.1 Quality Improvement

Quality improvement is an integral part of the QA process. The Laboratory staff works continuously to improve the elements of the quality system and to respond to changing circumstances. The R&IENL quality program is intended to equip the staff to implement a quality system which addresses each project or task and the responsibilities of those carrying out those projects and tasks. The quality staff shall continuously review the quality system and assess needs for staff training to increase knowledge and improve QA and QC skills. The QA Manager performs assessments, including audits, in order to strengthen good practices and bring areas requiring improvement to the attention of staff and management.

Audit and assessment reports are submitted to the Laboratory Director with copies to: R&IENL's Deputy Director, the CD whose program/activities/projects fall under, the appropriate QAC, and the ORIA QA Manager.

Tools such as customer feedback, reports to management, periodic review of documentation practices, data package review, and audits of work plans and QAPP involve the quality staff and management in identifying both good practices and those which need to be improved, changed, or discontinued.

All documents, including the QMP, the QAMs, and all SOPs are reviewed by the RO for each document, the Technical Reviewer, the Center QAC, the Center Director, the QA Manager, and the Director. They are reviewed and revised as described in Section 3.1.

11.2 Corrective Actions

Corrective action may be required whenever the results of a quality assessment are unacceptable, as when quality indicators fall outside predetermined rejection limits, or when an audit reveals deficiencies in any portion of the QA program.

The primary responsibility for corrective action belongs to management. A Center Director who delegates responsibilities to subordinates is still responsible for monitoring the actions of those subordinates and for ensuring that the results are satisfactory. The QA Manager and the Center QAC take an active role in resolving problems and all problems affecting more than one Center. The Director has the authority to require corrective action by the Center Directors.

When the results of an internal quality assessment are unacceptable, the responsible party must be notified. The QA Manager may also discover deficiencies as a result of other types of assessments, such as

- inter- and intra-laboratory comparison studies;
- internal performance and systems audits;
- QA Program audits conducted by the ORIA QA Manager; and independent audits.

In these cases, the QA Manager must notify the Director and responsible Center Director.

Project-specific corrective action requirements must be documented in QAPPs. The QAPP should describe the methods used to assess quality and the procedures to be followed when the results of an assessment are unsatisfactory.

11.3 Initiation of Corrective Actions

The first person who discovers a problem shall initiate the corrective action process by reporting the problem in writing to the QA Manager, the Center QAC, and the Center Director.

Corrective actions must be initiated when:

- There is a variation to or a deviation from an SOP, QAPP, QAM, or the QMP.
- There is a method, protocol, or work plan violation.
- When samples or extracts are lost or otherwise can't be handled by the usual procedure or protocol.
- When QC criteria are exceeded and control cannot be re-established by means defined in an SOP.
- When there is suspect data for any reason.
- When data are found to be flawed, of questionable validity, or in violation of GLP.
- In any other circumstances when an analyst, manager, or other staff deems it appropriate to request investigation of a circumstance impacting data quality.

11.4 Corrective Action Initiated by the QA Manager

The QA Manager must initiate corrective action by issuing a CAR corrective action memorandum, addressed to the appropriate Center Director, QAC, the Director, and other concerned parties, which describes the problem and provides a deadline for a formal response. The QA Manager also attaches a CAR form, per SOP RIE-101, to the memorandum and assigns it a unique number. The Center Director, or a subordinate with delegated responsibility, investigates the problem, identifies probable causes, and takes corrective action. The responsible party must report to the QA Manager the steps taken to solve the problem, and close out the CAR.

The QA Manager evaluates this CAR and may accept it or require testing to prove that the problem has been solved. The QA Manager tracks the progress of the corrective action until the problem has been resolved.

The QA Manager must maintain documentation of each corrective action. The file includes all related memoranda, paper copies of electronic mail messages, and any computer printouts of related data.

Corrective action must be taken immediately. The responsible party must issue a response to the CAR. When the QA Manager performs an audit, he or she must summarize the results in a memorandum addressed to the Director and the key staff members involved in the audit. If the QA Manager finds that corrective action is required, the audit report has the effect of a corrective action memorandum and requires formal written responses.

12.0 APPENDICES

12.1 Glossary
12.2 Acronyms
12.3 References
12.4 Revision 4 Crosswalk

Appendix 12.1: Glossary

accountability: Employees acknowledgment and assumption of responsibility for actions, products, decisions, and policies including the administration, governance, and implementation within the scope of the role or employment position and encompassing the obligation to report, explain and be answerable for resulting consequences.

accreditation: Official recognition and documentation of conformance to a standard; in particular, the recognition by an accrediting organization such as a state, that a laboratory conforms to specified standards.

accuracy: The degree of agreement between an observed value and an accepted reference value. Accuracy includes a combination of random error (imprecision) and systematic error (bias) components which are due to sampling and analytical operations; a data quality indicator. EPA recommends that this term not be used and that precision and bias be used to convey the information usually associated with accuracy.

activity: (for radionuclides) – The activity of a specified body of material is the mean rate of nuclear decay in the material, expressed as a number of nuclear transformations divided by time.

audit: A systematic evaluation to determine the conformance to quantitative specifications of some operational function or activity.

bias: A systematic error which is inherent in a method of measurement or caused by some artifact or idiosyncrasy of the measurement system. Biases may be either positive or negative and several kinds can exist concurrently, so that only net bias can be evaluated in many cases. Bias is measured as the difference between the limiting mean and the true value measured by a system that is in statistical control.

Chain-of-Custody (COC): An unbroken trail of accountability that ensures the physical security of samples, data, and records.

comparability: The degree to which different methods, data sets, and/or decisions agree or can be represented as similar; a data quality indicator.

control chart: A graph of some measurement plotted over time or sequence of sampling, together with control limit(s) and, usually, a central line and warning line(s).

data: plural of datum. An individual fact, statistic, or piece of information (datum) or a group or body of facts, information, statistics, or the like, either historical or derived by calculation or experimentation. Facts, information, statistics, or figures from which conclusions can be inferred.

data quality: The totality of features and characteristics of data that bears on their ability to satisfy a given purpose; the sum of the degrees of excellence for factors related to data.

data of known quality: Data are of known quality when the qualitative and quantitative components associated with their derivation are documented appropriately for their intended use, and such documentation is verifiable and defensible.

data quality objectives (DQO): Qualitative and quantitative statements of the overall level of uncertainty that a decision-maker is willing to accept in results or decisions derived from environmental data. DQOs provide the statistical framework for planning and managing environmental data operations consistent with the data user's needs.

data reduction: The process of transforming raw data by arithmetic or statistical calculations, standard curves, concentration factors, etc, and collation into a more useful form.

defensible: Able to withstand any reasonable challenge related to the veracity or integrity of laboratory documents and derived data.

documentation: The use of written evidence; a written record furnishing information that a procedure has been performed. When applied to environmentally related measurements it includes all calculations related to sampling design; all steps in the chain of custody where appropriate,; and all notes and raw data generated in the sampling, analysis, or data validation process.

document control: A systematic procedure for indexing documents by number, date, and revision number for distribution, archiving, storage, and retrieval.

environmental sample: A sample of any material that is collected from an environmental source.

environmentally related measurement: Any assessment of environmental concern generated through or for field, laboratory, or modeling processes and the value(s) obtained from such an assessment.

fraudulent practices: Intentional misrepresentation or deception of mission-supported activities such as data falsification, fabrication (dry-labbing), failure to follow procedure(s), etc.

error (measurement): The difference between a measured value and the true value of the parameter measured. It is due to random error and systematic error.

good laboratory practices (GLP): Either general guidelines or formal regulations for performing basic laboratory operations or activities that are known or believed to influence the quality and integrity of the results.

intralaboratory quality control: The routine activities and checks, such as periodic calibrations, duplicate analyses, and spiked samples, that are included in normal internal procedures to control the accuracy and precision of measurements.

management systems review (MSR): The qualitative assessment of data collection operation(s) and/or organization(s) to establish whether the prevailing quality management structure, practices, and procedures are adequate for ensuring that the type and quality of data needed and expected are obtained.

method: A body of procedures and techniques for performing a task (e.g., sampling, characterization, quantification) systematically presented in the order in which they are to be executed.

Proficiency Testing Sample (PT): A sample, the composition of which is unknown to the analyst and is provided to test whether the analyst/laboratory can produce analytical results within specified performance limits.

precision: The degree to which a set of observations or measurements of the same property, usually obtained under similar conditions, conform to themselves; a data quality indicator. Precision is usually expressed as standard deviation, variance, or range, in either absolute or relative terms.

protocol: A detailed written procedure for a field and/or laboratory operation (e.g., sampling, analysis) which must be strictly adhered to.

quality: The sum of features and properties/characteristics of a product or service that bear on its ability to satisfy stated or implied needs. The consistent conformance of a product or service to a given set of standards or expectations (i.e., ISO-9000).

quality assessment: The evaluation of environmental data to determine if they meet the quality criteria required for a specific application.

Quality Assurance (QA): An integrated system of activities involving planning, quality control, quality assessment, reporting, and quality improvement to ensure that a product or service meets defined standards of quality with a stated level of confidence.

quality assurance objectives: The limits on bias, precision, comparability, completeness, and representativeness defining the minimal acceptable levels of performance as determined by the data user's acceptable error bounds.

Quality Assurance Manual (QAM): A formal document describing quality assurance, quality control, and quality assessment activities for an operation.

Quality Assurance Project Plan (QAPP): A formal document describing the detailed quality control procedures by which the quality requirements defined for the data and decisions pertaining to a specific project are to be achieved.

quality control (QC): The overall system of technical activities whose purpose is to measure and control the quality of a product or service so that it meets the needs of users. The aim is to provide quality that is satisfactory, adequate, dependable, and economical.

Quality Management Plan (QMP): A formal document describing the management policies, objectives, principles, organizational authority, responsibilities, accountability, and implementation plan of an agency, organization, or laboratory for ensuring quality in its products and utility to its users.

raw data: Any original factual information from a measurement activity or study recorded in laboratory worksheets, records, memoranda, notes, or exact copies thereof and that are necessary for the reconstruction and evaluation of the report of the activity or study. Raw data may include photographs, microfilm or microfiche copies, computer printouts, magnetic media including dictated observations and recorded data from automated instruments. If exact copies of raw data have been prepared (e.g., tapes which have been transcribed verbatim, dated, and verified accurate by signature), the exact copy or exact transcript may be substituted.

records system: A written, documented group of procedures describing required records, steps for producing them, storage conditions, retention period, and circumstances for their destruction or other disposition.

representativeness: The degree to which data accurately and precisely represent the frequency distribution of a specific variable in the population.

reproducibility: The extent to which a method, test, or experiment yields the same or similar results when performed on sub-samples of the same sample by different analysts or laboratories.

review: The assessment of management/operational functions or activities to establish their conformance to qualitative specifications or requirements.

sample: A part of a larger whole or a single item of a group; a finite part or subset of a statistical population. A sample serves to provide data or information concerning the properties of the whole group or population.

sensitivity: The capability of a method or instrument to discriminate between measurement responses representing different levels of a variable of interest.

standard method: An assemblage of techniques and procedures based on consensus or other criteria, often evaluated for its reliability by collaborative testing and receiving organizational approval.

standard operating procedure (SOP): A written document which details the method of an operation, analysis, or action whose techniques and procedures are thoroughly prescribed and which is accepted as the method for performing certain routine or repetitive tasks.

technical systems audit: A thorough, systematic on-site, qualitative review of facilities, equipment, personnel, training, procedures, record keeping, data validation, data management, and reporting aspects of a total measurement system.

traceability: An unbroken trail of accountability for verifying or validating the chain-of-custody of samples, data, the documentation of a procedure, or the values of a standard.

uncertainty: A measure of the total variability associated with a process that includes the two major error components: systematic error (bias) and random error (imprecision.)

validated method: A method which has been determined to meet certain performance criteria for sampling and/or measurement operations.

Appendix 12.2: Acronyms

AAA	Anytime Anyplace Access
ANSI	American National Standards Institute
CAR	Corrective Action Report (formerly known as a Quality Action Report)
CERMER	Center for Environmental Restoration Monitoring and Emergency Response
CFR	Code of Federal Regulations
CIE	Center for Indoor Environments
CIO	Chief Information Officer
COOP	Continuity of Operations Plan
COR	Contracting Officer Representative
COTR	Contracting Officer Technical Representative
CRQA	Center for Radioanalysis and Quality Assurance
CTS	Customer Technology Services
DBA	Data base Administrator
DOE	Department of Energy
DQO	Data Quality Objective
ECMS	Enterprise Content Management System
EPA	Environmental Protection Agency
ERGS	Environmental Radiation Ground Scanning
FCO	Funds Control Officer
FOIA	Freedom of Information Act
FRA	Federal Records Act
FRMAC	Federal Radiological Monitoring and Assessment Center
GLP	Good Laboratory Practices
IA	Interagency Agreement
IAQ	Indoor Air Quality
IE	Indoor Environments
IQG	Information Quality Guidelines
IMO	Information Management Officer
ISO	Information Security Officer
IT	Information Technology
ITEP	Institute for Tribal Environmental Professionals
ITM	Information Technology Manager
LAN	Local Area Network
LIMS	Laboratory Information Management System
MAPEP	Mixed Analyte Performance Evaluation Program
MERL	Mobile Emergency Response Laboratory
MOU	Memorandum of Understanding
MSR	Management Systems Review
NAREL	National Air and Radiation Environmental Laboratory
NAU	Northern Arizona University
NIST	National Institute for Standards and Technology
NRC	Nuclear Regulatory Commission
NRF	National Response Framework
NRMP	National Records Management Program
OAM	Office of Acquisition Management
OAQPS	Office of Air Quality Planning and Standards
OAR	Office of Air and Radiation
OARM	Office of Acquisition and Resource Management
OEI	Office of Environmental Information
OIRM	Office of Information Resources Management
ORIA	Office of Radiation and Indoor Air
OSWER	Office of Solid Waste and Emergency Response

PO	Project Officer
PM	Project Manager
PT	Proficiency Testing
PST	Public Service Telecommunications
QA	Quality Assurance
QAARWP	Quality Assurance Annual Report and Work Plan
QA Manager	Quality Assurance Manager
QAC	Quality Assurance Coordinator
QAS	Quality Assurance Staff
QAM	Quality Assurance Manual
QAMT	Quality Assurance Management Team
QAPP	Quality Assurance Project Plan
QAR	Quality Action Report
QC	Quality Control
QMP	Quality Management Plan
QS	Quality Staff
QSA	Quality Systems Audit
R&IENL	Radiation and Indoor Environments National Laboratory
RCRA	Resource Conservation and Recovery Act
RERT	Radiological Emergency Response Team
RO	Responsible Official
RSM	Radiation Safety Manual
RSO	Radiation Safety Officer
SACO	Simplified Acquisitions Contracting Officer
SHEM	Safety, Health, and Environmental Manager
SHEMP	Safety, Health, and Environmental Management Program
SOP	Standard Operating Procedure
TAMS Center	Tribal Air Monitoring Support Center
WAM	Work Assignment Manager
WAN	Wide Area Network

Appendix 12.3: References

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11. *Quality Management Plan,* National Air and Radiation Environmental Laboratory, Montgomery, Alabama, September 2010
12. *Quality Management Plan*, Office of Radiation and Indoor Air, Washington, D.C., April 2008 (R3, August 2010)
13. Radiation Safety Manual, Radiation and Indoor Environmental National Laboratory (R&IENL), Las Vegas, Nevada.
14. EPA's Principles of Scientific Integrity, first issued by the Administrator on November 24, 1999.
14. Science Policy Council *Peer Review Handbook*, 3rd Edition (EPA/100/B-06/002), June 2006.

Appendix 12.4: Revision 4 Crosswalk

The following are a list of revisions to R&IENL's QMP (R3): now, R&IENL QMP (R4).

Item No.	Section	Revised From	Revised To
1	General	R3, Effective 11/21/2011	R4, Effective 3/9/2012
2	General		Defined acronyms, and made small edits.
5	General	Deleted: TAMS	Added: Radon/Gravimetric Laboratories
3	Pg. i, Document Control Form w Approvals	Malek Chatila	Paul Weeden
4	Pg. iii, Revision History	NAREL Acknowledgements	Deleted the NAREL Acknowledgements
6	Pg. 1, §1.3.1, Para. 2, Sent. 1	Deleted: technical direction of Superfund contractors and conducting comparative and/or confirmatory measurement studies.	Added: Superfund contractors and recommendations for technical direction to On Scene Coordinators (OSCs) on site investigations or verification of cleanups.
7	Pg. 2, §1.3.2, Para. 1	Added: NAU/ITEP (through a cooperative agreement) provides training and technical support to tribes. CIE provides limited particulate matter (PM) filter weighing analysis from CIE's Gravimetric Laboratory. Although the TAMS Center relationship between CIE and NAU/ITEP is a partnership, all data throughput generated by CIE is subject to CIE review; similarly with NAU/ITEP, All training and technical support is the responsibility of NAU/ITEP.	
8	Pg. 2, §1.3.2, Para. 2	Added: The measurement data is used to improve the customer's overall ability to accurately measure radon and is an important component in the Agency's efforts to reduce the public's risk to radiation exposure from radon gas and its progeny. CIE staff: conduct QA exposures to support quality assurance activities for States, EPA Regional offices, industry, and local governments; perform radon measurements in support of Environmental Justice surveys; and conduct bi-annual radon gas and radon decay product inter-comparisons to support industry proficiency programs.	
9	Pg. 2, §1.3.2, Para. 3	Added: systems in partnership with private proficiency programs, and support air quality investigations through an air sampler loan program	
10	Pg. 2, §1.4, Para. 1, Sent. 2	Added: PM2.5 gravimetric services	
11	Pg. 2, §1.4, Para. 2, Sent. 2	Deleted: currently in partnership with ITEP at NAU	
12	Pg. 3, §2.1, Item 1.	Environmental protection for public and employee health	Protect the environment and human health.
13	Pg. 3, §2.1, Item 2.	Compliance with the law and EPA policy	Compliance with Federal, State, and local laws and EPA policy requirements.
14	Pg. 3, §2.1, Item 3.	Quality of products and services through defensible data integrity	Quality of products and services through data defensibility.
15	Pg. 3, §2.1, Para 3, Sent. 2	Added: Verifiability	

16	Pg. 5, §2.3, Bullet 9	Deleted: R&IENL is in compliance with, and intends to remain in compliance with Federal, State, and local regulations regarding disposal of hazardous wastes.	Added: R&IENL operates under the Office of Research and Development's (Las Vegas, NV) Chemical Hygiene Plan for work performed at CHL.
17	Pg. 5, §2.4, Para. 3, Sent. 2	Deleted: QA Management Team	Added: QA Manager
18	Pg. 6, Figure 1	Added: Organizational flow arrows from R&IENL Director to CERMER, and CIE.	
19	Pg. 7, §2.5, Para. 5	Added: To assure the successful implementation of the R&IENL Quality System, R&IENL program managers (in addition to their duties delegated to them by the Director) must work collaboratively with the QA Manager. Collaboration includes regular communication to assure matters related to quality are adequately addressed.	
20	Pg. 7, §2.6, Sent. 1	Added: and scientific technical AND Other specific roles and responsibilities, in addition to those defined in this section, are defined throughout this document.	
21	Pg. 7, §2.6.1, Para. 1, Sent. 2	Added: – this appointment is done formally via memorandum.	
22	Pg. 7, §2.6.2 Para. 1	Added: The QA Manager is selected based on criteria which includes, but is not limited to: a science background or BS degree; demonstrated knowledge of Agency and R&IENL quality requirements and policies; working knowledge of programs within R&IENL; and must possess the ability to effectively communicate verbally and in writing. AND – this includes revision of the QMP, and R&IENL-level SOPs.	
23	Pg. 12, §3, Bullet 4	Added: It is staffs responsibility to assure	
24	Pg. 12, §3, Bullet 5	Deleted: organizational units	Added: programs, activities
25	Pg. 10, §2.6.6.2, Second to last sentence	Added: assures that all documentation, as they relate to health and safety are in place, and are reviewed annually or as needed (e.g., chemical hygiene plan)	
26	Pg. 11, §2.6.6.9	Added: The QARF must be reviewed and approved by the R&IENL QA Manager.	
27	Pg. 13, §3.1.1, Para. 2 AND Pg. 13, §3.1.1, Para. 2 Sent. 6	Deleted: The QA Manager has primary responsibility for the QMP. The QMP is reviewed, distributed, and revised in accordance with provisions of this document. The document is reviewed annually by the QAMT, and final authority belongs to the Director and QA Manager.	Added: The Laboratory Director has primary responsibility for the QMP. The QA Manager has primary responsibility for review, compliance with the ORIA QMP, and distribution of the QMP. The document is reviewed annually by the QAMT, and final authority belongs to the Director. AND The R&IENL QA Manager
28	Pg. 16, §3.16, Para. 2	Added: Information disseminated through the use of websites, must undergo review and approval for accuracy and to ensure consistency with quality policy and documentation.	
29	Pg. 19, §4.2, Para. 3, Sent. 2	Added: The CD must identify these documents in a formal manner, through memo or signed form for each person stating the documents which he or she agrees to read and comply with.	
30	Pg. 21, §4.8, Sent. 2	Added: on the Personnel Training Needs Assessment form (P:\DO\Quality\Documents\Forms\Personnel Training Needs Assessment.docx)	

31	Pg. 21, §4.10, Para. 1	Added: It is the responsibility of the Center Director to assure staff has provided sufficient copies for QA Manager and Center record maintenance. And: Copies of training certificates will be provided by staff to the Center Director (or a CD-delegated official).	
32	Pg. 21, §4.10, Para. 3	Deleted: and emergency response training.	
33	Pg. 23, §5.5	Deleted: Approving Official	Added: appropriate Center Director and Deputy Director
34	Pg. 23, §5.5	The AO for R&IENL is the Deputy Director.	The designated Approving Officials (AOs) for R&IENL are the Deputy Director and the FCO.
35	Pg. 24, §6.2, Para. 1, Last sentence	Added: or initials	
36	Pg. 26, §7.1.2, Section Title	Server and/or Telecommunication	Network Engineer and System
37	Pg. 27, §7.2, Para. 7	Added: Any software developed must initially be requested, in writing, to the IT Manager with a design proposal (as identified above). The software requires thorough testing plans by both the developer and the requestor, which must be approved by the IT Manager, the Center Director, the QAC, and the QA Manager. The testing plans must show that the software is being tested against the original specifications. The developer and requestor must provide a written certification that the software was tested according to the plan, along with a narrative of any problems encountered during testing. Documentation package that includes the design request, approved testing plan(s), written certification of approval, etc. must be maintained by the appropriate Center QAC.	
38	Pg. 30, §9.1.2, last sent.	Deleted: formally	Added: in writing
39	Pg. 31, §10.1, Bullet 4	Deleted: An independent review process must be used for all data. Guidance in QAMs and SOPs will be written to describe generic review and approval procedures for data produced during field activities for routine and emergency situations.	Added: An independent review process must be used when reviewing data. Requirements are provided in Center specific QAMs and SOPs that describe generic review and approval procedures for data produced during field activities for routine and emergency situations.
40	Pg. 31, §10.1, Last Bullet	Deleted: Currently, there are SOPs in place for review and approval of radioanalytic data produced in the R&IENL fixed laboratory.	
41	Pg. 32, §10.3, Sent. 2	Deleted: copies of correspondence related to QA, documentation of new methods,	
42	Pg. 32, §10.3, Sent. 3	Deleted: keeps	Added: and QACs maintain
43	Pg. 32, §11.1, Para.2	Added: Audit and assessment reports are submitted to the Laboratory Director with copies to: R&IENL's Deputy Director, the CD whose program/activities/projects fall under, the appropriate QAC, and the ORIA QA Manager.	
44	Pg. 32, §11.1, Para.3, Last Sentence	Deleted: per	Added: described in
45	Pg. 33, §11.2, Para.3, Sent. 2	Deleted: (e.g., staff member, PM, WAM, or Center Director) must notify the Center Director, the Center QAC, and the QA Manager as appropriate	Added: must be notified.
46	Pg. 33, §11.4, Para. 1,	Deleted: may	Added: must

	Sent. 1		
47	Pg. 36		Added: **fraudulent practices:** Intentional misrepresentation or deception of mission-supported activities such as data falsification, fabrication (dry-labbing), failure to follow procedure(s), etc.
48	Pg. 40, Appendix 12.2: References, #5.		Added: EPA's Principles of Scientific Data Integrity. 2012. http://www.epa.gov/osa/pdfs/epa-principles-of-scientific-integrity.pdf

National Center for Radiation Field Operations (NCRFO)

Center for Radiation Preparedness and Response (CRPR)

Quality Assurance Manual

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National Center for Radiation Field Operations

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